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REGULATIONS for the ADMINISTRATION and ENFORCEMENT of The RADIATION CONTROL for HEALTH and SAFETY ACT of 1968

April 1988

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

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REGULATIONS for the ADMINISTRATION
and
ENFORCEMENT of The RADIATION CONTROL
for
HEALTH and SAFETY ACT of 1968

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(Supersedes HEW Publication FDA 80-8035)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

INTRODUCTION

The Radiation Control for Health and Safety Act was signed by the President on October 18, 1968. The purpose of this Act was to protect the public from unnecessary exposure to radiation from electronic products. Radiation covered in the Act was called "electronic product radiation" and was defined to mean any ionizing or nonionizing electromagnetic or particulate radiation or any sonic, infrasonic, or ultrasonic wave which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

The provisions of the Act give the Secretary, Department of Health and Human Services (formerly Department of Health, Education, and Welfare), authority to establish and carry out an electronic product radiation control program which shall include performance standards for electronic products. The regulations contained herein have been promulgated under that authority. The Center for Devices and Radiological Health (formerly the Bureau of Radiological Health) is responsible for the day-to-day operation in carrying out the Act's mandate for an electronic product radiation control program. A principal objective of the program is to protect the public health through setting and enforcing electronic product radiation emission performance standards.

This compilation is revised periodically, and efforts are made to provide an accurate reproduction of the regulations. This publication contains those regulations published in the FEDERAL REGISTER on March 1987. There were no substantive changes to these regulations up to the date of this publication. The only difference is the name change for the Center for Devices and Radiological Health. To maintain current information on amendments or deletions to 21 CFR Subchapter J, and for the official regulations, the reader should consult the latest issuances of the FEDERAL REGISTER and the Code of Federal Regulations, Title 21. Some significant changes to the performance standard for Diagnostic X-ray Equipment are anticipated to be published in late 1989.

Information relative to the clarification or implementation of any part of the enclosed material can be obtained by calling (301) 427-7175 or writing to the Office of Compliance (HFZ-300), Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, Maryland 20857.

**THESE REGULATIONS ARE SUBJECT TO CHANGE
WITH DUE NOTICE IN THE
FEDERAL REGISTER**

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SUBCHAPTER I—[RESERVED]

SUBCHAPTER J—RADIOLOGICAL HEALTH

PART 1000—GENERAL

Subpart A—General Provisions

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1000.60 Recommendation on administratively required dental x-ray examinations.

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SOURCE: 38 FR 28624, Oct. 15, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 1000.1 General.

References in this Subchapter J to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

[50 FR 33688, Aug. 20, 1985]

§ 1000.3 Definitions.

As used in this Subchapter J:

(a) "Electronic product radiation" means—

(1) Any ionizing or nonionizing electromagnetic or particulate radiation, or

(2) Any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

(b) "Electromagnetic radiation" includes the entire electromagnetic spectrum of radiation of any wavelength. The electromagnetic spectrum illustrated in Figure 1 includes, but is not limited to, gamma rays, X-rays, ultraviolet, visible, infrared, microwave, radiowave, and low frequency radiations.

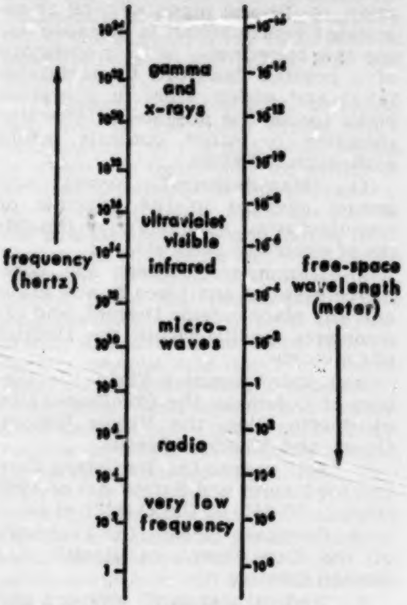

Figure 1. The Electromagnetic Spectrum

(c) "Particulate radiation" is defined as charged particles such as protons, electrons, alpha particles, heavy particles, etc., which have sufficient kinetic energy to produce ionization or atomic or electron excitation by collision, electrical attractions or electrical repulsion or uncharged particles such as neutrons, which can initiate a nuclear transformation or liberate charged particles having sufficient kinetic energy to produce ionization or atomic or electron excitation by collision.

(d) "Infrasonic, sonic (or audible) and ultrasonic waves" refer to energy transmitted as an alteration (pressure, particle displacement or density) in a property of an elastic medium (gas, liquid or solid) that can be detected by an instrument or listener.

(e) "Electronic product" means (1) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (2) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in paragraph (e)(1) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation.

(f) "Manufacturer" means any person engaged in the business of manufacturing, assembling, or importing of electronic products.

(g) "Commerce" means (1) commerce between any place in any State and any place outside thereof, and (2) commerce wholly within the District of Columbia.

(h) "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

(i) "Act" means the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.).

(j) "Secretary" means the Secretary of the Department of Health and Human Services.

(k) "Federal standard" means a performance standard issued pursuant to section 358 of the Act.

(l) The term "dealer" means a person engaged in the business of offering electronic products for sale to purchasers, without regard to whether such person is or has been primarily engaged in such business, and includes persons who offer such products for lease or as prizes or awards.

(m) The term "distributor" means a person engaged in the business of offering electronic products for sale to dealers without regard to whether such person is or has been primarily or customarily engaged in such business.

(n) The term "purchaser" means the first person who, for value, or as an award or prize, acquires an electronic product for purposes other than resale, and also includes a person who leases an electronic product for purposes other than subleasing.

(o) The term "model" means any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.

Subpart B—Statements of Policy and Interpretation

§ 1000.15 Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968.

The following listed electronic products are intended to serve as illustrative examples of sources of electronic product radiation to which the regulations of this part apply.

(a) Examples of electronic products which may emit X-rays and other ionizing electromagnetic radiation, electrons, neutrons, and other particulate radiation include:

Ionizing electromagnetic radiation:
  Television receivers.
  Accelerators.
  X-ray machines (industrial, medical, research, educational).
Particulate radiation and ionizing electromagnetic radiation:
  Electron microscopes.
  Neutron generators.

(b) Examples of electronic products which may emit ultraviolet, visible, infrared, microwaves, radio and low frequency electromagnetic radiation include:

Ultraviolet:
  Biochemical and medical analyzers.
  Tanning and therapeutic lamps.
  Sanitizing and sterilizing devices.
  Black light sources.
  Welding equipment.
Visible:
  White light devices.
Infrared:
  Alarm systems.
  Diathermy units.
  Dryers, ovens, and heaters.

Microwave:
  Alarm systems.
  Diathermy units.
  Dryers, ovens, and heaters.
  Medico-biological heaters.
  Microwave power generating devices.
  Radar devices.
  Remote control devices.
  Signal generators.
Radio and low frequency:
  Cauterizers.
  Diathermy units.
  Power generation and transmission equipment.
  Signal generators.
  Electromedical equipment.

(c) Examples of electronic products which may emit coherent electromagnetic radiation produced by stimulated emission include:

Laser:
  Art-form, experimental and educational devices.
  Biomedical analyzers.
  Cauterizing, burning and welding devices.
  Cutting and drilling devices.
  Communications transmitters.
  Rangefinding devices.
Maser:
  Communications transmitters.

(d) Examples of electronic products which may emit infrasonic, sonic, and ultrasonic vibrations resulting from operation of an electronic circuit include:

Infrasonic:
  Vibrators.
Sonic:
  Electronic oscillators.
  Sound amplification equipment.
Ultrasonic:
  Cauterizers.
  Cell and tissue disintegrators.
  Cleaners.
  Diagnostic and nondestructive testing equipment.
  Ranging and detection equipment.

Subpart C—Radiation Protection Recommendations

§ 1000.50 Recommendation for the use of specific area gonad shielding on patients during medical diagnostic x-ray procedures.

Specific area gonad shielding covers an area slightly larger than the region of the gonads. It may therefore be used without interfering with the objectives of the examination to protect the germinal tissue of patients from radiation exposure that may cause genetic mutations during many medical x-ray procedures in which the gonads lie within or are in close proximity to the x-ray field. Such shielding should be provided when the following conditions exist:

(a) The gonads will lie within the primary x-ray field, or within close proximity (about 5 centimeters), despite proper beam limitation. Except as provided in paragraph (b) or (c) of this section:

(1) Specific area testicular shielding should always be used during those examinations in which the testes usually are in the primary x-ray field, such as examinations of the pelvis, hip, and upper femur;

(2) Specific area testicular shielding may also be warranted during other examinations of the abdominal region in which the testes may lie within or in close proximity to the primary x-ray field, depending upon the size of the patient and the examination techniques and equipment employed. Some examples of these are: Abdominal, lumbar spine and lumbosacral spine examinations, intravenous pyelograms, and abdominal scout film for barium enemas and upper GI series. Each x-ray facility should evaluate its procedures, techniques, and equipment and compile a list of such examinations for which specific area testicular shielding should be routinely considered for use. As a basis for judgment, specific area testicular shielding should be considered for all examinations of male patients in which the pubic symphysis will be visualized on the film;

(3) Specific area gonad shielding should never be used as a substitute for careful patient positioning, the use of correct technique factors and film processing, or proper beam limitation (confinement of the x-ray field to the area of diagnostic interest), because this could result in unnecessary doses to other sensitive tissues and could adversely affect the quality of the radiograph; and

(4) Specific area gonad shielding should provide attenuation of x-rays at least equivalent to that afforded by 0.25 millimeter of lead.

(b) The clinical objectives of the examination will not be compromised.

(1) Specific area testicular shielding usually does not obscure needed information except in a few cases such as oblique views of the hip, retrograde urethrograms and voiding cystourethrograms, visualization of the rectum and, occasionally, the pubic symphysis. Consequently, specific area testicular shielding should be considered for use in the majority of x-ray examinations of male patients in which the testes will lie within the primary beam or within 5 centimeters of its edge. It is not always possible to position shields on male patients so that no bone is obscured. Therefore, if all bone structure of the pelvic area must be visualized for a particular patient, the use of shielding should be carefully evaluated. The decision concerning the applicability of shielding for an individual patient is dependent upon consideration of the patient's0unique anthropometric characteristics and the diagnostic information needs of the examination.

(2) The use of specific area ovarian shielding is frequently impractical at present because the exact location of the ovaries is difficult to estimate, and the shield may obscure visualization of portions of adjacent structures such as the spine, ureters, and small and large bowels. However, it may be possible for practitioners to use specific area ovarian shielding during selected views in some examinations.

(c) The patient has a reasonable reproductive potential.

(1) Specific area shielding need not be used on patients who cannot or are not likely to have children in the future.

(2) The following table of statistical data regarding the average number of children expected by potential parents in various age categories during their remaining lifetimes is provided for x-ray facilities that wish to use it as a basis for judging reproductive potential:

EXPECTED NUMBER OF FUTURE CHILDREN VERSUS AGE OF POTENTIAL PARENT [1]

Age	Male parent	Female parent
Fetus	2.6	2.6
0 to 4	2.6	2.5
5 to 9	2.7	2.5
10 to 14	2.7	2.6
15 to 19	2.7	2.6
20 to 24	2.6	2.2
25 to 29	2.0	1.4
30 to 34	1.1	.6
35 to 39	.5	.2
40 to 44	.2	.04
45 to 49	.07	0
50 to 54	.03	0
55 to 64	.01	0
Over 65	0	0

[1] Derived from data published by the National Center for Health Statistics, "Final Natality Statistics 1970," HRA 74-1120, vol. 22, No. 12, Mar. 20, 1974.

(Sec. 356, 82 Stat. 1174-1176 (42 U.S.C. 263d))

[41 FR 30328, July 23, 1976; 41 FR 31812, July 30, 1976]

§ 1000.55 Recommendation for quality assurance programs in diagnostic radiology facilities.

(a) *Applicability.* Quality assurance programs as described in paragraph (c) of this section are recommended for all diagnostic radiology facilities.

(b) *Definitions.* As used in this section, the following definitions apply:

(1) "Diagnostic radiology facility" means any facility in which an x-ray system(s) is used in any procedure that involves irradiation of any part of the human body for the purpose of diagnosis or visualization. Offices of individual physicians, dentists, podiatrists, and chiropractors, as well as mobile laboratories, clinics, and hospitals are all examples of diagnostic radiology facilities.

(2) "Quality assurance" means the planned and systematic actions that provide adequate confidence that a diagnostic x-ray facility will produce consistently high quality images with minimum exposure of the patients and healing arts personnel. The determination of what constitutes high quality will be made by the facility producing the images. Quality assurance actions include both "quality control" techniques and "quality administration" procedures.

(3) "Quality assurance program" means an organized entity designed to provide "quality assurance" for a diagnostic radiology facility. The nature and extent of this program will vary with the size and type of the facility, the type of examinations conducted, and other factors.

(4) "Quality control techniques" are those techniques used in the monitoring (or testing) and maintenance of the components of an x-ray system. The quality control techniques thus are concerned directly with the equipment.

(5) "Quality administration procedures" are those management actions intended to guarantee that monitoring techniques are properly performed and evaluated and that necessary corrective measures are taken in response to monitoring results. These procedures provide the organizational framework for the quality assurance program.

(6) "X-ray system" means an assemblage of components for the controlled production of diagnostic images with x-rays. It includes minimally an x-ray high voltage generator, an x-ray control, a tube-housing assembly, a beam-limiting device, and the necessary supporting structures. Other components that function with the system, such as image receptors, image processors, view boxes, and darkrooms, are also parts of the system.

(c) *Elements.* A quality assurance program should contain the elements listed in paragraphs (c)(1) through (10) of this section. The extent to which each element of the quality assurance program is implemented should be determined by an analysis of the facility's objectives and resources conducted by its qualified staff or by qualified outside consultants. The extent of implementation should be determined on the basis of whether the expected benefits in radiation exposure reduction, improved image quality, and/or financial savings will compensate for the resources required for the program.

(1) *Responsibility.* (i) Responsibility and authority for the overall quality assurance program as well as for monitoring, evaluation, and corrective measures should be specified and recorded in a quality assurance manual.

(ii) The owner or practitioner in charge of the facility has primary responsibility for implementing and maintaining the quality assurance program.

(iii) Staff technologists will generally be delegated a basic quality assurance role by the practitioner in charge. Responsibility for specific quality control monitoring and maintenance techniques or quality administration procedures may be assigned, provided that the staff technologists are qualified by training or experience for these duties. The staff technologists should also be responsible for identifying problems or potential problems requiring actions beyond the level of their training. They should bring these problems to the attention of the practitioner in charge, or his or her representative, so that assistance in solving the problems may be obtained from inside or outside the facility.

(iv) In facilities where they are available, physicists, supervisory technologists, or quality control technologists should have a major role in the quality assurance program. Such specialized personnel may be assigned responsibility for day-to-day administration of the program, may carry out monitoring duties beyond the level of training of the staff technologist or, if desired by the facility, may relieve the staff technologists of some or all of their basic monitoring duties. Staff service engineers may also be assigned responsibility for certain preventive or corrective maintenance actions.

(v) Responsibility for certain quality control techniques and corrective measures may be assigned to personnel qualified by training or experience, such as consultants or industrial representatives, from outside of the facility, provided there is a written agreement clearly specifying these services.

(vi) In large facilities, responsibility for long-range planning of quality assurance goals and activities should be assigned to a quality assurance committee as described in paragraph (c)(9) of this section.

(2) *Purchase specifications.* Before purchasing new equipment, the staff

of the diagnostic radiology facility should determine the desired performance specifications for the equipment. Initially, these specifications may be stated in terms of the desired performance of the equipment, or prospective vendors may be informed solely of the functions the equipment should be able to perform and asked to provide the performance specifications of items from their equipment line that can perform these functions. In either case, the responses of the prospective vendors should serve as the basis for negotiations to establish the final purchase specifications, taking into account the state of the art and balancing the need for the specified performance levels with the cost of the equipment to meet them. The final purchase specifications should be in writing and should include performance specifications. The availability of experienced service personnel should also be taken into consideration in making the final purchase decisions. Any understandings with respect to service personnel should be incorporated into the purchase specifications. After the equipment is installed, the facility should conduct a testing program, as defined in its purchase specifications, to ensure that the equipment meets the agreed upon specifications, including applicable Federal and State regulatory requirements. The equipment should not be formally accepted until any necessary corrections have been made by the vendor. The purchase specifications and the records of the acceptance testing should be retained throughout the life of the equipment for comparison with monitoring results in order to assess continued acceptability of performance.

(3) *Monitoring and maintenance.* A routine quality control monitoring and maintenance system incorporating state-of-the-art procedures should be established and conducted on a regular schedule. The purpose of monitoring is to permit evaluation of the performance of the facility's x-ray system(s) in terms of the standards for image quality established by the facility (as described in paragraph (c)(4) of this section) and compliance with applicable Federal and State regulatory requirements. The maintenance program should include corrective maintenance to eliminate problems revealed by monitoring or other means before they have a serious deleterious impact on patient care. To the extent permitted by the training of the facility staff, the maintenance program should also include preventive maintenance, which could prevent unexpected breakdowns of equipment and disruption of departmental routine.

(i) The parameters to be monitored in a facility should be determined by that facility on the basis of an analysis of expected benefits and cost. Such factors as the size and resources of the facility, the type of examinations conducted, and the quality assurance problems that have occurred in that or similar facilities should be taken into account in establishing the monitoring system. The monitoring frequency should also be based upon need and can be different for different parameters.

(ii) Although the parameters to be monitored will vary somewhat from facility to facility, every diagnostic radiology facility should consider monitoring the following five key components of the x-ray system:

(*a*) Film processing.

(*b*) Basic performance characteristics of the x-ray unit.

(*c*) Cassettes and grids.

(*d*) View boxes.

(*e*) Darkroom.

(iii) Examples of parameters of the above-named components and of more specialized equipment that may be monitored are as follows:

(*a*) For film processing:

An index of speed.
An index of contrast.
Base plus fog.
Solution temperatures.
Film artifact identification.

(*b*) For basic performance characteristics of the x-ray unit:

(*1*) For fluoroscopic x-ray units:

Table-top exposure rates.
Centering alignment.
Collimation.
kVp accuracy and reproducibility.
mA accuracy and reproducibility.
Exposure time accuracy and reproducibility.

Reproducibility of x-ray output.
Focal spot size consistency.
Half-value layer.
Representative entrance skin exposures.

(*2*) For image-intensified systems:

Resolution.
Focusing.
Distortion.
Glare.
Low contrast performance.
Physical alignment of camera and collimating lens.

(*3*) For radiographic x-ray units:

Reproducibility of x-ray output.
Linearity and reproducibility of mA stations.
Reproducibility and accuracy of timer stations.
Reproducibility and accuracy of kVp stations.
Accuracy of source-to-film distance indicators.
Light/x-ray field congruence.
Half-value layer.
Focal spot size consistency.
Representative entrance skin exposures.

(*4*) For automatic exposure control devices:

Reproducibility.
kVp compensation.
Field sensitivity matching.
Minimum response time.
Backup timer verification.

(*c*) For cassettes and grids:

(*1*) For cassettes:

Film/screen contact.
Screen condition.
Light leaks.
Artifact identification.

(*2*) For grids:

Alignment and focal distance.
Artifact identification.

(*d*) For view boxes:

Consistency of light output with time.
Consistency of light output from one box to another.
View box surface conditions.

(*e*) For darkrooms:

Darkroom integrity.
Safe light conditions.

(*f*) For specialized equipment:

(*1*) For tomographic systems:

Accuracy of depth and cut indicator.
Thickness of cut plane.
Exposure angle.
Completeness of tomographic motion.
Flatness of tomographic field.
Resolution.
Continuity of exposure.
Flatness of cassette.
Representative entrance skin exposures.

(*2*) For computerized tomography:

Precision (noise).
Contrast scale.
High and low contrast resolution.
Alignment.
Representative entrance skin exposures.

(iv) The maintenance program should include both preventive and corrective aspects.

(*a*) *Preventive maintenance.* Preventive maintenance should be performed on a regularly scheduled basis with the goal of preventing breakdowns due to equipment failing without warning signs detectable by monitoring. Such actions have been found cost effective if responsibility is assigned to facility staff members. Possible preventive maintenance procedures are visual inspection of the mechanical and electrical characteristics of the x-ray system (covering such things as checking conditions of cables, watching the tomographic unit for smoothness of motion, assuring cleanliness with respect to spilling of contaminants in the examination room or the darkroom, and listening for unusual noises in the moving parts of the system), following the manufacturer's recommended procedures for cleaning and maintenance of the equipment, and regular inspection and replacement of switches and parts that routinely wear out or fail. The procedures included would depend upon the background of the staff members available. Obviously, a large facility with its own service engineers can do more than an individual practitioner's office.

(*b*) *Corrective maintenance.* For maximum effectiveness, the quality assurance program should make provision, as described in paragraph (c)(5) of this section, for ascertaining whether potential problems are developing. If potential or actual problems are detected, corrective maintenance should be carried out to eliminate them before they cause a major impact on patient care.

(*4*) *Standards for image quality.* Standards of acceptable image quality should be established. Ideally, these should be objective, e.g., acceptability limits for the variations of parameter values, but they may be subjective, e.g., the opinions of professional personnel, in cases where adequate objective standards cannot be defined. These standards should be routinely reviewed and redefined as needed, as described in paragraph (c)(10) of this section.

(5) *Evaluation.* The facility's quality assurance program should include means for two levels of evaluation.

(i) On the first level, the results of the monitoring procedures should be used to evaluate the performance of the x-ray system(s) to determine whether corrective actions are needed to adjust the equipment so that the image quality consistently meets the standards for image quality. This evaluation should include analysis of trends in the monitoring data as well as the use of the data to determine the need for corrective actions on a day-by-day basis. Comparison of monitoring data with the purchase specifications and acceptance testing results for the equipment in question is also useful.

(ii) On the second level, the facility quality assurance program should also include means for evaluating the effectiveness of the program itself. Possible means include ongoing studies of the retake rate and the causes of the repeated radiographs, examination of equipment repair and replacement costs, subjective evaluation of the radiographs being produced, occurrence and reasons for complaints by radiologists, and analysis of trends in the results of monitoring procedures such as sensitometric studies. Of these, ongoing studies of the retake rate (reject rate) and its causes are often the most useful and may also provide information of value in the first level of evaluation. Such studies can be used to evaluate potential for improvement, to make corrections, and to determine whether the corrective actions were effective. The number of rejects should be recorded daily or weekly, depending on the facility's analysis of its needs. Ideally, the reasons for the rejection should also be determined and recorded. Should determining these reasons be impossible on a regular basis with the available staff, the analysis should be done for a 2-week period after major changes have occurred in diagnostic procedures or the x-ray system and at least semi-annually.

(6) *Records.* The program should include provisions for the keeping of records on the results of the monitoring techniques, any difficulties detected, the corrective measures applied to these difficulties, and the effectiveness of these measures. The extent and form of these records should be determined by the facility on the basis of its needs. The facility should view these records as a tool for maintaining an effective quality assurance program and not view the data in them as an end in itself but rather as a beginning. For example, the records should be made available to vendors to help them provide better service. More importantly, the data should be the basis for the evaluation and the reviews suggested in paragraphs (c)(5) and (10) of this section.

(7) *Manual.* A quality assurance manual should be written in a format permitting convenient revision as needed and should be made readily available to all personnel. The content of the manual should be determined by the facility staff, but the following items are suggested as providing essential information:

(i) A list of the individuals responsible for monitoring and maintenance techniques.

(ii) A list of the parameters to be monitored and the frequency of monitoring.

(iii) A description of the standards, criteria of quality, or limits of acceptability that have been established for each of the parameters monitored.

(iv) A brief description of the procedures to be used for monitoring each parameter.

(v) A description of procedures to be followed when difficulties are detected to call these difficulties to the attention of those responsible for correcting them.

(vi) A list of the publications in which detailed instructions for monitoring and maintenance procedures can be found. Copies of these publications should also be readily available to the entire staff, but they should be separate from the manual. (Publications providing these instructions can usually be obtained from FDA or private sources, although the facility may wish to make some modifications to meet its needs more effectively.)

(vii) A list of the records, with sample forms, that the facility staff has decided should be kept. The facility staff should also determine and note in the manual the length of time each type of record should be kept before discarding.

(viii) A copy of each set of purchase specifications developed for new equipment and the results of the acceptance testing for that equipment.

(8) *Training.* The program should include provisions for appropriate training for all personnel with quality assurance responsibilities. This should include both training provided before the quality assurance responsibilities are assumed and continuing education to keep the personnel up-to-date. Practical experience with the techniques conducted under the supervision of experienced instructors, either in the facility or in a special program, is the most desirable type of training. The use of self-teaching materials can be an adequate substitute for supervised instruction, especially in continuing education programs, if supervised instruction is not available.

(9) *Committee.* A facility whose size would make it impractical for all staff members to meet for planning purposes should consider the establishment of a quality assurance committee whose primary function would be to maintain lines of communication among all groups with quality assurance and/or image production or interpretation responsibilities. For maximum communication, all departments of the facility with x-ray equipment should be represented. The committee may also be assigned policy-making duties such as some or all of the following:

Assign quality assurance responsibilities; maintain acceptable standards of quality; periodically review program effectiveness, etc. Alternatively, the duties of this committee could be assigned to an already-existing committee such as the Radiation Safety Committee. In smaller facilities, all staff members should participate in the committee's tasks. The Quality Assurance Committee should report directly to the head of the radiology department, or, in facilities where more than one department operates x-ray equipment, to the chief medical officer of the facility. The committee should meet on a regular basis.

(10) *Review.* The facility's quality assurance program should be reviewed by the Quality Assurance Committee and/or the practitioner in charge to determine whether its effectiveness could be improved. Items suggested for inclusion in the review include:

(i) The reports of the monitoring and maintenance techniques to ensure that they are being performed on schedule and effectively. These reports should be reviewed at least quarterly.

(ii) The monitoring and maintenance techniques and their schedules to ensure that they continue to be appropriate and in step with the latest developments in quality assurance. They should be made current at least annually.

(iii) The standards for image quality to ensure that they are consistent with the state-of-the-art and the needs and resources of the facility. These standards should be evaluated at least annually.

(iv) The results of the evaluations of the effectiveness of the quality assurance actions to determine whether changes need to be made. This determination should be made at least annually.

(v) The quality assurance manual should also be reviewed at least annually to determine whether revision is needed.

[44 FR 71737, Dec. 11, 1979]

§ 1000.60 Recommendation on administratively required dental x-ray examinations.

(a) The Food and Drug Administration recommends that dental x-ray examinations be performed only after careful consideration of the dental or other health needs of the patient, that is, when the patient's dentist or physician judges them to be necessary for diagnosis, treatment, or prevention of disease. Administratively required dental x-ray examinations are those required by a remote third party for reasons not related to the patient's immediate dental needs. These x-ray examinations are usually a source of unnecessary radiation exposure to the patient. Because any unnecessary radiation exposure should be avoided, third parties should not require dental x-ray examinations unless they can demonstrate that such examinations provide a direct clinical benefit to the patient, and the patient's dentist or physician agrees with that assessment.

(b) Some examples of administrative x-ray examinations that should not be required by third parties are those intended solely:

(1) To monitor insurance claims or detect fraud;

(2) To satisfy a prerequisite for reimbursement;

(3) To provide training or experience;

(4) To certify qualifications or competence.

(c) This recommendation is not intended to preclude dental x-ray examinations ordered by the attending practitioner, based on the patient's history or physical examination, or those performed on selected populations shown to have significant yields of previously undiagnosed disease. This recommendation is also not intended to preclude the administrative use by third parties of dental radiographs that are taken on the order of the patient's dentist or physician as a necessary part of the patient's clinical care.

[45 FR 40978, June 17, 1980]

PART 1002—RECORDS AND REPORTS

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1002.61 List of specific product groups.

AUTHORITY: Sec. 360A, 82 Stat. 1182-84; 42 U.S.C. 263i, 263j, unless otherwise noted.

SOURCE: 38 FR 28625, Oct. 15, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 1002.1 Applicability.

The provisions of this part are applicable to manufacturers, dealers, and distributors of electronic products as specified herein, but, except for § 1002.20, are not applicable to:

(a) Manufacturers of electronic products intended solely for export if such product is labeled or tagged to show that the product is intended for export, and the product meets all the applicable requirements of the country to which such product is intended for export:

(b) Manufacturers of electronic products listed in § 1002.61 if sold exclusively to other manufacturers for use as components of electronic products to be sold to purchasers, with the exception that the provisions are applicable to those manufacturers certifying components of diagnostic x-ray systems pursuant to provisions of § 1020.30(c) of this chapter.

(c) Manufacturers of electronic products which are intended for use by the U.S. Government and whose function or design cannot be divulged by the manufacturer for reasons of national security, as evidenced by government security classification.

(d) Assemblers of diagnostic x-ray equipment subject to the provisions of § 1020.30(d) of this chapter, provided the assembler has submitted the report required by § 1020.30(d) (1) or (2) of this chapter and retains a copy of such report for a period of five years from its date.

[38 FR 31828, Nov. 19, 1973]

§ 1002.2 Definitions.

As used in this part:

(a) The term "dealer" means a person engaged in the business of offering electronic products for sale to purchasers, without regard to whether such person is or has been primarily engaged in such business, and includes persons who offer such products for lease or as prizes or awards.

(b) The term "distributor" means a person engaged in the business of offering electronic products for sale to dealers without regard to whether such person is or has been primarily or customarily engaged in such business.

(c) The term "purchaser" means the first person who, for value, or as an award or prize, acquires an electronic product for purposes other than resale, and also includes a person who leases an electronic product for purposes other than subleasing.

(d) The term "accidental radiation occurrence" means a single event or series of events occurring in the course of the manufacturing, testing, or use of any electronic product which has resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a direct result of the manufacturing, testing, or use of that product.

(e) The term "model" means any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.

§ 1002.3 Records and reports on components.

Records and reports required for products listed in § 1002.61 shall include information on all components which the manufacturer may provide with the listed product and which affect the quantity, quality, or direction of the radiation emissions.

§ 1002.4 Confidentiality of information.

The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to this part, which concerns or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code, except that such information may be disclosed to other officers or employees of the Department and of the other agencies concerned with carrying out the requirements of the Act. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

§ 1002.7 Submision of data and reports.

All submissions such as reports, test data, product descriptions, and other information required by this part, or voluntarily submitted to the Director, Bureau of Radiological Health, shall be filed with the number of copies as prescribed by the Director, Bureau of Radiological Health, and shall be signed by the person making the submission.

(a) In addition to the requirements of this part, all material submitted to the Director, Bureau of Radiological Health, shall be submitted pursuant to the provisions of Part 20—Public Information, of this chapter.

(b) Where guides or instructions have been issued by the Director, Bureau of Radiological Health, for the submission of material required by this part such as test data, initial and annual reports, and reports of model changes, the material submitted shall conform to the applicable reporting guide or instruction to the extent that it is possible or appropriate to do so. Where it is not feasible or where it would not be appropriate to conform to any portion of a prescribed reporting guide or instruction, an alternate format for providing the information requested by that portion of the guide or instruction may be used provided the submitter of such information submits adequate explanation and justification for use of an alternate format. If the Director, Bureau of Radiological Health, determines that such justification is inadequate and that it is feasible or appropriate to conform to the prescribed reporting guide or instruction, he may require resubmission of the information in conformance with the reporting guide or instruction.

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f))

[42 FR 18062, Apr. 5, 1977]

Subpart B—Required Manufacturers' Reports for Listed Electronic Products

§ 1002.10 Initial reports.

Every manufacturer of a product listed under § 1002.61, shall submit an initial report to the Director, Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, in accordance with this section. The report shall be submitted within 90 days following the effective date of listing such product under § 1002.61 or prior to the introduction of such product into commerce, whichever is later. The report shall be distinctly marked "Initial Report of (Name of Manufacturer)" and shall:

(a) State in the report for each model of a listed product whether the report is submitted pursuant to paragraph (a), (b), or (c) of § 1002.61.

(b) Identify each model of the listed product together with sufficient information concerning the manufacturer's code or other system of labeling sufficient to enable the Secretary to determine the place of manufacture.

(c) Describe the function, operational characteristics affecting radiation emissions, and intended and known uses of each model of the listed product.

(d) State the standards or design specifications, if any, for each model with respect to electronic product radiation safety. Reference may be made to a Federal standard, if applicable.

(e) For each model, describe the physical or electrical characteristics such as shielding, or electronic circuitry, etc., incorporated into the product in order that the standards or specifications reported pursuant to paragraph (d) of this section are met.

(f) Describe the methods and procedures employed, if any, in testing and measuring each model with respect to electronic product radiation safety including the control of unnecessary, secondary, or leakage electronic product radiation, the applicable quality control procedures used for each model, and the basis for selecting such testing and quality control procedures.

(g) For those products which may produce increased radiation with aging, describe the methods and procedures used, and frequency of testing each model for durability and stability with respect to electronic product radiation safety. Include the basis for selecting such methods and procedures, or for determining that such testing and quality control procedures are not necessary.

(h) Provide sufficient results of the testing and measuring of electronic product radiation safety and of the quality control procedures described in accordance with paragraphs (f) and (g) of this section to enable the Secretary to determine the effectiveness of the methods and procedures used to accomplish the stated purposes.

(i) Report for each model, all warning signs, labels and instructions, for installation, operation, and use which relate to electronic product radiation safety.

(j) Provide upon request such other information as the Secretary may reasonably require to enable him to determine whether the manufacturer has acted or is acting in compliance with the Act and any standards prescribed thereunder, and to enable the Secretary to carry out the purposes of the Act.

[38 FR 28625, Oct. 15, 1973, as amended at 39 FR 16228, May 8, 1974; 40 FR 10175, Mar. 5, 1975]

§ 1002.11 Annual reports.

(a) Every manufacturer of products listed under § 1002.61(b) and (c) shall submit an annual report summarizing the contents of the records required to be maintained by § 1002.30(a).

(b) The first annual report shall be submitted by September 1, 1971, with subsequent reports due annually thereafter. Such reports shall cover the 12-month period ending on June 30 preceding the due date of the report.

§ 1002.12 Reports of model changes.

Prior to the introduction into commerce of a new or modified model of a product listed in § 1002.61 for which an initial report under § 1002.10 was required, each manufacturer shall submit a report with respect to such new or modified model containing any changes in the information submitted in the initial report.

Subpart C—Manufacturers' Reports on Accidental Radiation Occurrences

§ 1002.20 Reporting of accidental radiation occurrences.

(a) Manufacturers of electronic products shall, where reasonable grounds for suspecting that such an incident has occurred, immediately report to the Director, Bureau of Radiological Health, all accidental radiation occurrences reported to or otherwise known to the manufacturer and arising from the manufacturing, testing, or use of any product introduced or intended to be introduced into commerce by such manufacturer. Reasonable grounds include, but are not necessarily limited to, professional, scientific, or medical facts or opinions documented or otherwise, that conclude or lead to the conclusion that such an incident has occurred.

(b) Such reports shall be addressed to the Director, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20857, and the reports and their envelopes shall be distinctly marked "Report on § 1002.20" and shall contain all of the following information where known to the manufacturer:

(1) The nature of the accidental radiation occurrence;

(2) The location at which the accidental radiation occurrence occurred;

(3) The manufacturer, type, and model number of the electronic product or products involved;

(4) The circumstances surrounding the accidental radiation occurrence, including causes;

(5) The number of persons involved, adversely affected, or exposed during the accidental radiation occurrence, the nature and magnitude of their exposure and/or injuries and, if requested by the Director, Bureau of Radiological Health, the names of the persons involved;

(6) The actions, if any, which may have been taken by the manufacturer, to control, correct, or eliminate the causes and to prevent reoccurrence; and

(7) Any other pertinent information with respect to the accidental radiation occurrence.

(c) If a manufacturer is required to report to the Director under paragraph (a) of this section and also is required to report under Part 803 of this chapter, the manufacturer shall report in accordance with Part 803. If a manufacturer is required to report to the Director under paragraph (a) of this section and is not required to report under Part 803, the manufacturer shall report in accordance with paragraph (a) of this section.

(Secs. 502(t), 510, 519, 701(a), 704 (a) and (e), 52 Stat. 1055, 76 Stat. 792-795 as amended, 90 Stat. 564-565, 578, 581 (21 U.S.C. 352(t), 360, 360i, 371(a), 374 (a) and (e)); secs. 215, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n))

[38 FR 28625, Oct. 15, 1973 and 49 FR 36351, Sept. 14, 1984]

Subpart D—Manufacturers' Records

§ 1002.30 Records to be maintained by manufacturers.

(a) Manufacturers of products listed under paragraphs (b) and (c) of § 1002.61 shall establish and maintain the following records with respect to such products:

(1) Description of the quality control procedures with respect to electronic product radiation safety.

(2) Records of the results of tests for electronic product radiation safety, including the control of unnecessary, secondary or leakage electronic product radiation, the methods, devices, and procedures used in such tests, and the basis for selecting such methods, devices, and procedures.

(3) For those products displaying aging effects which may increase electronic product radiation emission, records of the results of tests for durability and stability of the product, and the basis for selecting these tests.

(4) Copies of all written communications between the manufacturer and dealers, distributors, and purchasers concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance, or testing of the listed product.

(b) In addition to the records required by paragraph (a) of this section, manufacturers of products listed in paragraph (c) of § 1002.61 shall establish and maintain the following records with respect to such products:

(1) A record of the manufacturer's distribution of products in a form which will enable the tracing of specific products or production lots to distributors or to dealers in those instances in which the manufacturer distributes directly to dealers.

(2) Records received from dealers or distributors pursuant to § 1002.41.

§ 1002.31 Preservation and inspection of records.

(a) Every manufacturer required to maintain records pursuant to this part, including records received pursuant to § 1002.41, shall preserve such records for a period of 5 years from the date of the record.

(b) Upon reasonable notice by an officer or employee duly designated by the Department, manufacturers shall permit such officer or employee to inspect appropriate books, records, papers, and documents as are relevant to determining whether the manufacturer has acted or is acting in compliance with Federal standards.

(c) Upon request of the Director, Bureau of Radiological Health, a manufacturer of products listed in paragraph (c) of § 1002.61 shall submit to the Director, copies of the records required to be maintained by paragraph (b) of § 1002.30.

Subpart E—Dealer and Distributor Records

§ 1002.40 Records to be obtained by dealers and distributors.

(a) Dealers and distributors of electronic products listed in § 1002.61(c), for which there are applicable Federal standards under this subchapter and for which the retail price is not less than $50, shall obtain such information as is necessary to permit tracing of specific products to specific purchasers.

(b) Such information shall include:

(1) The name and mailing address of the distributor, dealer, or purchaser to whom the product was transferred.

(2) Identification and brand name of the product.

(3) Model number and serial or other identification number of the product.

(4) Date of sale, award, or lease.

(c) The information obtained pursuant to this section shall be forwarded immediately to the appropriate manufacturer of the electronic product, or preserved as prescribed in § 1002.41.

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f))

[38 FR 28625, Oct. 15, 1973, as amended at 42 FR 18063, Apr. 5, 1977]

§ 1002.41 Disposition of records obtained by dealers and distributors.

(a) Information obtained by dealers and distributors pursuant to § 1002.40 shall immediately be forwarded to the appropriate manufacturer unless:

(1) The dealer or distributor elects to hold and preserve such information and to immediately furnish it to the manufacturer when advised by the manufacturer or the Director, Bureau of Radiological Health, that such information is required for purposes of section 359 of the Act; and

(2) The dealer or distributor, upon making the election under paragraph (a)(1) of this section, promptly notifies the manufacturer of such election; such notification shall be in writing and shall identify the dealer or distributor and the electronic product or products for which the information is being accumulated and preserved.

(b) Every dealer or distributor who elects to hold and preserve information required pursuant to § 1002.40 shall preserve the information for a period of 5 years from the date of the sale, award, or lease of the product, or until the dealer or distributor discontinues dealing in, or distributing the product, whichever is sooner. If the dealer or distributor discontinues dealing in, or distributing the product, such information as obtained pursuant to § 1002.40 shall be furnished at that time, or before, to the manufacturer of the product.

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f))

[38 FR 28625, Oct. 15, 1973, as amended at 42 FR 18063, Apr. 5, 1977]

§ 1002.42 Confidentiality of records furnished by dealers and distributors.

All information furnished to manufacturers by dealers and distributors pursuant to this part shall be treated by such manufacturers as confidential information which may be used only as necessary to notify persons pursuant to section 359 of the Act.

Subpart F—Exemptions from Records and Reports Requirements

§ 1002.50 Special exemptions.

(a) Manufacturers of electronic products listed under paragraphs (b) and (c) of § 1002.61 may submit to the Director, Bureau of Radiological Health, with or subsequent to the submission of the initial report required by § 1002.10, a request, together with accompanying justification, that a product be exempted from the annual reporting and recordkeeping requirements. In addition to other information which may be required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested:

(1) Cannot emit electronic product radiation in sufficient intensity or of such quality under any conditions of use or product failure to be hazardous; or

(2) Is produced in such small numbers as to negate the need for continuous recordkeeping and reporting, and is to be used by trained individuals who are knowledgeable of the hazards involved in such use.

(b) The Director, Bureau of Radiological Health, may exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with paragraph (a) of this section or such other information which he may possess or may require of the manufacturer if he determines that such exemption is in keeping with the purposes of the Act.

§ 1002.51 Exemptions for manufacturers of products intended for the U.S. Government.

Upon application therefor by the manufacturer, the Director, Bureau of Radiological Health, may exempt from the provisions of this part a manufacturer of any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

Subpart G—Codes for Reporting Listed Electronic Products

§ 1002.61 List of specific product groups.

(a) *Group A.* (1) Ultrasonic products.

(2) Microwave heating equipment not listed in paragraph (c) of this section.

(3) High voltage vacuum switches, high voltage rectifier tubes, shunt regulator tubes, and cathode ray tubes which are intended to be operated at voltages greater than 5,000 volts but less than 15,000 volts.

(4) Ultraviolet lamps and products containing such lamps intended for irradiation of any part of the living human body by light of wavelength in air less than 320 nanometers to perform a diagnostic or therapeutic function.

(b) *Group B.* (1) Television receivers which, on or after the effective date of this subpart, meet the Federal standard in effect on June 1, 1971, provided also that the voltage on the cathode ray tube and any other vacuum tube component cannot exceed 15,000 volts under the test conditions required by the Federal standard at that time.

(2) High voltage vacuum switches, high voltage rectifier tubes, shunt regulator tubes, and cathode ray tubes, which are intended to operate at voltages of 15,000 volts or greater.

(c) *Group C.* (1) Products subject to Federal standards prescribed under this subchapter except for television receivers described in paragraph (b)(1) of this section.

(2) Products which are intended to produce x-radiation.

(3) Industrial dielectric heaters, including radiofrequency (RF) sealers, and electromagnetic (EM) induction heating equipment that operate in the frequency range from 2 megahertz to 500 megahertz.

(4) Microwave diathermy machines.

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f))

[38 FR 28625, Oct. 15, 1973, as amended at 40 FR 10175, Mar. 5, 1975; 41 FR 27316, July 2, 1976; 44 FR 65357, Nov. 9, 1979; 45 FR 47615, July 15, 1980]

PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

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Sec.

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1003.2 Defect in an electronic product.
1003.5 Effect of regulations on other laws.

Subpart B—Discovery of Defect or Failure to Comply

1003.10 Discovery of defect or failure of compliance by manufacturer; notice requirements.
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Subpart C—Notification

1003.20 Notification by the manufacturer to the Secretary.
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1003.31 Granting the exemption.

AUTHORITY: Sec. 359, 82 Stat. 1180; 42 U.S.C. 263g, unless otherwise noted.

SOURCE: 38 FR 28628, Oct. 15, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 1003.1 Applicability.

The provisions of this part are applicable to electronic products which were manufactured after October 18, 1968.

§ 1003.2 Defect in an electronic product.

For the purpose of this part, an electronic product shall be considered to have a defect which relates to the safety of use by reason of the emission of electronic product radiation if:

(a) It is a product which does not utilize the emission of electronic product radiation in order to accomplish its purpose, and from which such emissions are unintended, and as a result of its design, production or assembly;

(1) It emits electronic product radiation which creates a risk of injury, including genetic injury, to any person, or

(2) It fails to conform to its design specifications relating to electronic radiation emissions; or

(b) It is a product which utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended, and as a result of its design, production or assembly it;

(1) Fails to conform to its design specifications relating to the emission of electronic product radiation; or

(2) Without regard to the design specifications of the product, emits electronic product radiation unnecessary to the accomplishment of its primary purpose which creates a risk of injury, including genetic injury to any person; or

(3) Fails to accomplish the intended purpose.

§ 1003.5 Effect of regulations on other laws.

The remedies provided for in this subchapter shall be in addition to and not in substitution for any other remedies provided by law and shall not relieve any person from liability at common law or under statutory law.

Subpart B—Discovery of Defect or Failure to Comply

§ 1003.10 Discovery of defect or failure of compliance by manufacturer; notice requirements.

Any manufacturer who discovers that any electronic product produced, assembled, or imported by him, which product has left its place of manufacture, has a defect or fails to comply with an applicable Federal standard shall:

(a) Immediately notify the Secretary in accordance with § 1003.20, and

(b) Except as authorized by § 1003.30, furnish notification with reasonable promptness to the following persons:

(1) The dealers or distributors to whom such product was delivered by the manufacturer; and

(2) The purchaser of such product and any subsequent transferee of such product (where known to the manufacturer or where the manufacturer upon reasonable inquiry to dealers, distributors, or purchasers can identify the present user).

(c) If a manufacturer is required to notify the Secretary under paragraph (a) of this section and also is required to report to the Food and Drug Administration under Part 803 of this chapter, the manufacturer shall report in accordance with Part 803. If a manufacturer is required to notify the Secretary under paragraph (a) of this section and is not required to report to the Food and Drug Administration under Part 803, the manufacturer shall notify the Secretary in accordance with paragraph (a) of this section.

(Secs. 502(t), 510, 519, 701(a), 704 (a) and (e), 52 Stat. 1055, 76 Stat. 792-795 as amended, 90 Stat. 564-565, 578, 581 (21 U.S.C. 352(t), 360, 360i, 371(a), 374 (a) and (e)); secs. 215, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n))

[38 FR 28628, Oct. 15, 1973 and 49 FR 36351, Sept. 14, 1984]

§ 1003.11 Determination by Secretary that product fails to comply or has a defect.

(a) If, the Secretary, through testing, inspection, research, or examination of reports or other data, determines that any electronic product does not comply with an applicable Federal standard issued pursuant to the Act or has a defect, he shall immediately notify the manufacturer of the product in writing specifying:

(1) The defect in the product or the manner in which the product fails to comply with the applicable Federal standard;

(2) The Secretary's findings, with references to the tests, inspections, studies, or reports upon which such findings are based;

(3) A reasonable period of time during which the manufacturer may present his views and evidence to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of electronic product radiation.

The manufacturer shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter.

(b) Every manufacturer who receives a notice under paragraph (a) of this section shall immediately advise the Secretary in writing of the total number of such product units produced and the approximate number of such product units which have left the place of manufacture.

(c) If, after the expiration of the period of time specified in the notice, the Secretary determines that the product has a defect or does not comply with an applicable Federal standard and the manufacturer has not applied for an exemption, he shall direct the manufacturer to furnish the notification to the persons specified in § 1003.10(b) in the manner specified in § 1003.21. The manufacturer shall within 14 days from the date of receipt of such directive furnish the required notification.

[38 FR 28628, Oct. 15, 1973, as amended at 41 FR 48269, Nov. 2, 1976; 42 FR 15676, Mar. 22, 1977]

Subpart C—Notification

§ 1003.20 Notification by the manufacturer to the Secretary.

The notification to the Secretary required by § 1003.10(a) shall be confirmed in writing and, in addition to other relevant information which the Secretary may require, shall include the following:

(a) Identification of the product or products involved;

(b) The total number of such product units so produced, and the approximate number of such product units which have left the place of manufacture;

(c) The expected usage for the product if known to the manufacturer;

(d) A description of the defect in the product or the manner in which the product fails to comply with an applicable Federal standard;

(e) An evaluation of the hazards reasonably related to defect or the failure to comply with the Federal standard;

(f) A statement of the measures to be taken to repair such defect or to bring the product into compliance with the Federal standard;

(g) The date and circumstances under which the defect was discovered; and

(h) The identification of any trade secret information which the manufacturer desires kept confidential.

§ 1003.21 Notification by the manufacturer to affected persons.

(a) The notification to the persons specified in § 1003.10(b) shall be in writing and, in addition to other relevant information which the Secretary may require, shall include:

(1) The information prescribed by § 1003.20 (a), (d), and instructions with respect to the use of the product pending the correction of the defect;

(2) A clear evaluation in nontechnical terms of the hazards reasonably related to any defect or failure to comply; and

(3) The following statement:

> The manufacturer will, without charge, remedy the defect or bring the product into compliance with each applicable Federal standard in accordance with a plan to be approved by the Secretary of Health and Human Services, the details of which will be included in a subsequent communication to you.

Provided, That if at the time the notification is sent, the Secretary has approved a plan for the repair, replacement or refund of the product, the notification may include the details of the approved plan in lieu of the above statement.

(b) The envelope containing the notice shall not contain advertising or other extraneous material, and such mailings will be made in accordance with this section.

(1) No. 10 white envelopes shall be used, and the name and address of the manufacturer shall appear in the upper left corner of the envelope.

(2) The following statement is to appear in the far left third of the envelope in the type and size indicated and in reverse printing, centered in a red rectangle 3¾ inches wide and 2¼ inches high:

IMPORTANT—ELECTRONIC PRODUCT
RADIATION WARNING

The statement shall be in three lines, all capitals, and centered. "Important" shall be in 36-point Gothic Bold type. "Electronic Product" and "Radiation Warning" shall be in 36-point Gothic Condensed type.

(3) Envelopes with markings similar to those prescribed in this section shall not be used by manufacturers for

mailings other than those required by this part.

(c) The notification shall be sent:

(1) By certified mail to purchasers of the product and to subsequent transferees.

(2) By certified mail or other more expeditious means to dealers and distributors.

(d) Where products were sold under a name other than that of the manufacturer of the product, the name of the individual or company under whose name the product was sold may be used in the notification required by this section.

§ 1003.22 Copies of communications sent to purchasers, dealers or distributors.

(a) Every manufacturer of electronic products shall furnish to the Secretary a copy of all notices, bulletins, or other communications sent to the dealers or distributors of such manufacturers or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any defect in such product or any failure of such product to comply with an applicable Federal standard.

(b) In the event the Secretary deems the content of such notices to be insufficient to protect the public health and safety, the Secretary may require additional notice to such recipients, or may elect to make or cause to be made such notification by whatever means he deems appropriate.

Subpart D—Exemptions From Notification Requirements

§ 1003.30 Application for exemption from notification requirements.

(a) A manufacturer may at the time of giving the written confirmation required by § 1003.20 or within 15 days of the receipt of any notice from the Secretary pursuant to § 1003.11(a), apply for an exemption from the requirement of notice to the persons specified in § 1003.10(b).

(b) The application for exemption shall contain the information required by § 1003.20 and in addition shall set forth in detail the grounds upon which the exemption is sought.

§ 1003.31 Granting the exemption.

(a) If, in the judgment of the Secretary, the application filed pursuant to § 1003.30 states reasonable grounds for an exemption from the requirement of notice, the Secretary shall give the manufacturer written notice specifying a reasonable period of time during which he may present his views and evidence in support of the application.

(b) Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable Federal standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Secretary determines that an oral presentation is desirable. Where such evidence includes nonclinical laboratory studies, the data submitted shall include, with respect to each such study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. When such evidence includes clinical investigations involving human subjects, the data submitted shall include, with respect to each clinical investigation either a statement that each investigation was conducted in compliance with the requirements set forth in Part 56 of this chapter, or a statement that the investigation is not subject to such requirements in accordance with § 56.104 or § 56.105, and a statement that each investigation was conducted in compliance with the requirements set forth in Part 50 of this chapter.

(c) If, during the period of time afforded the manufacturer to present his views and evidence, the manufacturer proves to the Secretary's satisfaction that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the Secretary shall issue an exemption from the requirement of notification to the manufacturer and shall notify the manufacturer in writing specifying:

(1) The electronic product or products for which the exemption has been issued; and

(2) Such conditions as the Secretary deems necessary to protect the public health and safety.

(d) Any person who contests denial of an exemption shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter.

(Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 601, 701(a), 706, and 801, 52 Stat. 1049-1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360i); secs. 215, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended; (42 U.S.C. 216, 262, 263b-263n); secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 701(a), 706, and 801, 52 Stat. 1049-1053 as amended, 1055, 1058 as amended, 55 Stat 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-407 as amended, 76 Stat. 794-795 as amended, 90 Stat. 540-560, 562-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 371(a), 376 and 381); secs. 215, 301, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 241, 262, 263b-263n))

[38 FR 28628, Oct. 15, 1973, as amended at 41 FR 48269, Nov. 2, 1976; 42 FR 15676, Mar. 22, 1977; 50 FR 7518, Feb. 22, 1985]

PART 1004—REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC PRODUCTS

Sec.

1004.1 Manufacturer's obligation to repair, replace, or refund cost of electronic products.

1004.2 Plans for the repair of electronic products.

1004.3 Plans for the replacement of electronic products.

1004.4 Plans for refunding the cost of electronic products.

1004.6 Approval of plans.

AUTHORITY: Sec. 359, 82 Stat. 1180; 42 U.S.C. 263g.

SOURCE: 38 FR 28629, Oct. 15, 1973, unless otherwise noted.

§ 1004.1 Manufacturer's obligation to repair, replace, or refund cost of electronic products.

(a) If any electronic product fails to comply with an applicable Federal standard or has a defect and the notification specified in § 1003.10(b) of this chapter is required to be furnished, the manufacturer of such product shall;

(1) Without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied; or

(2) Replace such product with a like or equivalent product which complies with each applicable Federal standard and which has no defect relating to the safety of its use; or

(3) Make a refund of the cost of the product to the purchaser.

(b) The manufacturer shall take the action required by this section in accordance with a plan approved by the Secretary pursuant to § 1004.6.

§ 1004.2 Plans for the repair of electronic products.

Every plan for bringing an electronic product into conformity with applicable Federal standards or for remedying any defect in such product shall be submitted to the Secretary in writing, and in addition to other relevant information which the Secretary may require, shall include:

(a) Identification of the product involved.

(b) The approximate number of defective product units which have left the place of manufacture.

(c) The specific modifications, alterations, changes, repairs, corrections, or adjustments to be made to bring the product into conformity or remedy any defect.

(d) The manner in which the operations described in paragraph (c) will be accomplished, including the procedure for obtaining access to, or possession of, the products and the location where such operations will be performed.

(e) The technical data, test results or studies demonstrating the effectiveness of the proposed remedial action.

(f) A time limit, reasonable in light of the circumstances, for completion of the operations.

(g) The system by which the manufacturer will provide reimbursement for any transportation expenses incurred in connection with having such product brought into conformity or having any defect remedied.

(h) The text of the statement which the manufacturer will send to the persons specified in § 1003.10(b) of this chapter informing such persons;

(1) That the manufacturer, at his expense, will repair the electronic product involved,

(2) Of the method by which the manufacturer will obtain access to or possession of the product to make such repairs,

(3) That the manufacturer will reimburse such persons for any transportation expenses incurred in connection with making such repairs, and

(4) Of the manner in which such reimbursement will be effected.

(i) An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of the plan, including the number of electronic products repaired.

§ 1004.3 Plans for the replacement of electronic products.

Every plan for replacing an electronic product with a like or equivalent product shall be submitted to the Secretary in writing, and in addition to other relevant information which the Secretary may require, shall include:

(a) Identification of the product to be replaced.

(b) A description of the replacement product in sufficient detail to support the manufacturer's contention that the replacement product is like or equivalent to the product being replaced.

(c) The approximate number of defective product units which have left the place of manufacture.

(d) The manner in which the replacement operation will be effected including the procedure for obtaining possession of the product to be replaced.

(e) A time limit, reasonable in light of the circumstances for completion of the replacement.

(f) The steps which the manufacturer will take to insure that the defective product will not be reintroduced into commerce, until it complies with each applicable Federal standard and has no defect relating to the safety of its use.

(g) The system by which the manufacturer will provide reimbursement for any expenses for transportation of such product incurred in connection with effecting the replacement.

(h) The text of the statement which the manufacturer will send to the persons specified in § 1003.10(b) of this chapter informing such persons;

(1) That the manufacturer, at its expense, will replace the electronic product involved,

(2) Of the method by which the manufacturer will obtain possession of the product and effect the replacement,

(3) That the manufacturer will reimburse such persons for any transportation expenses incurred in connection with effecting such replacement, and

(4) Of the manner in which such reimbursement will be made.

(i) An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of the plan, including the number of electronic products replaced.

§ 1004.4 Plans for refunding the cost of electronic products.

Every plan for refunding the cost of an electronic product shall be submitted to the Secretary in writing, and in addition to other relevant information which the Secretary may require, shall include:

(a) Identification of the product involved.

(b) The approximate number of defective product units which have left the place of manufacture.

(c) The manner in which the refund operation will be effected including the procedure for obtaining possession of the product for which the refund is to be made.

(d) The steps which the manufacturer will take to insure that the defective products will not be reintroduced into commerce, until it complies with each applicable Federal standard and has no defect relating to the safety of its use.

(e) A time limit, reasonable in light of the circumstances, for obtaining the product and making the refund.

(f) A statement that the manufacturer will refund the cost of such product together with the information the manufacturer has used to determine the amount of the refund.

(g) The text of the statement which the manufacturer will send to the persons specified in § 1003.10(b) of this chapter informing such persons;

(1) That the manufacturer, at his expense, will refund the cost of the electronic product plus any transportation costs,

(2) Of the amount to be refunded exclusive of transportation costs,

(3) Of the method by which the manufacturer will obtain possession of the product and make the refund.

(h) An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of the plan, including the number of refunds made.

§ 1004.6 Approval of plans.

If, after review of any plan submitted pursuant to this subchapter, the Secretary determines that the action to be taken by the manufacturer will expeditiously and effectively fulfill the manufacturer's obligation under § 1004.1 in a manner designed to encourage the public to respond to the proposal, the Secretary will send written notice of his approval of such plan to the manufacturer. Such approval may be conditioned upon such additional terms as the Secretary deems necessary to protect the public health and safety. Any person who contests denial of a plan shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter.

[38 FR 28629, Oct. 15, 1973, as amended at 41 FR 48269, Nov. 2, 1976; 42 FR 15676, Mar. 22, 1977]

PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

Subpart A—General Provisions

Sec.
1005.1 Applicability.
1005.2 Definitions.
1005.3 Importation of noncomplying goods prohibited.

Subpart B—Inspection and Testing

1005.10 Notice of sampling.
1005.11 Payment for samples.

Subpart C—Bonding and Compliance Procedures

1005.20 Hearing.
1005.21 Application for permission to bring product into compliance.
1005.22 Granting permission to bring product into compliance.
1005.23 Bonds.
1005.24 Costs of bringing product into compliance.
1005.25 Service of process on manufacturers.

AUTHORITY: Secs. 215, 356, 58 Stat. 690, 82 Stat. 1174; 42 U.S.C. 216, 263d, unless otherwise noted.

SOURCE: 38 FR 28630, Oct. 15, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 1005.1 Applicability.

(a) The provisions of §§ 1005.1 through 1005.24 are applicable to electronic products which are subject to the standards prescribed under this subchapter and are offered for importation into the United States.

(b) Section 1005.25 is applicable to every manufacturer of electronic products offering an electronic product for importation into the United States.

(Secs. 356, 360, 82 Stat. 1174-1176, 1181-1182 (42 U.S.C. 263d, 263h))

[38 FR 28630, Oct. 15, 1973, as amended at 45 FR 81739, Dec. 12, 1980]

§ 1005.2 Definitions.

As used in this part:

The term "owner" or "consignee" means the person who has the rights of a consignee under the provisions of sections 483, 484, and 485 of the Tariff

Act of 1930, as amended (19 U.S.C. 1483, 1484, 1485).

§ 1005.3 Importation of noncomplying goods prohibited.

The importation of any electronic product for which standards have been prescribed under section 358 of the Act (42 U.S.C. 263f) shall be refused admission into the United States unless there is affixed to such product a certification in the form of a label or tag in conformity with section 358(h) of the Act (42 U.S.C. 263f(h)). Merchandise refused admission shall be destroyed or exported under regulations prescribed by the Secretary of the Treasury unless a timely and adequate petition for permission to bring the product into compliance is filed and granted under §§ 1005.21 and 1005.22.

Subpart B—Inspection and Testing

§ 1005.10 Notice of sampling.

When a sample of a product to be offered for importation has been requested by the Secretary, the District Director of Customs having jurisdiction over the shipment shall, upon the arrival of the shipment, procure the sample and shall give to its owner or consignee prompt notice of the delivery or of the intention to deliver such sample to the Secretary. If the notice so requires, the owner or consignee will hold the shipment of which the sample is typical and not release such shipment until he receives notice of the results of the tests of the sample from the Secretary, stating that the product is in compliance with the requirements of the Act. The District Director of Customs will be given the results of the tests. If the Secretary notifies the District Director of Customs that the product does not meet the requirements of the Act, the District Director of Customs shall require the exportation or destruction of the shipment in accordance with customs laws.

§ 1005.11 Payment for samples.

The Department of Health and Human Services will pay for all import samples of electronic products rendered unsalable as a result of testing, or will pay the reasonable costs of repackaging such samples for sale, if the samples are found to be in compliance with the requirements of the Radiation Control for Health and Safety Act of 1968. Billing for reimbursement shall be made by the owner or consignee to the Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20857. Payment for samples will not be made if the sample is found to be in violation of the Act, even though subsequently brought into compliance pursuant to terms specified in a notice of permission issued under § 1005.22.

Subpart C—Bonding and Compliance Procedures

§ 1005.20 Hearing.

(a) If, from an examination of the sample or otherwise, it appears that the product may be subject to a refusal of admission, the Secretary shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony unless the owner or consignee indicates his intention to bring the product into compliance. Upon timely request, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article and may be introduced orally or in writing.

(b) If the owner or consignee submits or indicates his intention to submit an application for permission to perform such action as is necessary to bring the product into compliance with the Act, such application shall include the information required by § 1005.21.

(c) If the application is not submitted at or prior to the hearing, the Secretary may allow a reasonable time for filing such application.

§ 1005.21 Application for permission to bring product into compliance.

Application for permission to perform such action as is necessary to bring the product into compliance with the Act may be filed only by the owner, consignee, or manufacturer and, in addition to any other information which the Secretary may reasonably require, shall:

(a) Contain a detailed proposal for bringing the product into compliance with the Act;

(b) Specify the time and place where such operations will be effected and the approximate time for their completion; and

(c) Identify the bond required to be filed pursuant to § 1005.23.

§ 1005.22 Granting permission to bring product into compliance.

(a) When permission contemplated by § 1005.21 is granted, the Secretary shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of a representative of the Department of Health and Human Services;

(4) A reasonable time limit for completing the operations; and

(5) Such other conditions as he finds necessary to maintain adequate supervision and control over the product.

(b) Upon receipt of a written request for an extension of time to complete the operations necessary to bring the product into compliance, the Secretary may grant such additional time as he deems necessary.

(c) The notice of permission may be amended upon a showing of reasonable grounds thereof and the filing of an amended application for permission with the Secretary.

(d) If ownership of a product included in a notice of permission changes before the operations specified in the notice have been completed, the original owner will remain responsible under its bond, unless the new owner has executed a superseding bond on customs Form 7601 and obtained a new notice.

(e) The Secretary will notify the District Director of Customs having jurisdiction over the shipment involved, of the determination as to whether or not the product has in fact been brought into compliance with the Act.

§ 1005.23 Bonds.

The bond required under section 360(b) of the Act shall be executed by the owner or consignee on the appropriate form of a customs single-entry bond, customs Form 7551 or term bond, customs Form 7553 or 7595, containing a condition for the redelivery of the shipment or any part thereof not complying with the laws and regulations governing its admission into the commerce of the United States upon demand of the District Director of Customs and containing a provision for the performance of any action necessary to bring the product into compliance with all applicable laws and regulations. The bond shall be filed with the District Director of Customs.

§ 1005.24 Costs of bringing product into compliance.

The costs of supervising the operations necessary to bring a product into compliance with the Act shall be paid by the owner or consignee who files an application pursuant to § 1005.21 and executes a bond under section 360(b) of the Act. Such costs shall include:

(a) Travel expenses of the supervising officer;

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law;

(c) *Service fees*: (1) The charge for the services of the supervising officer, which shall include administrative support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-11/4 employee, except that such services performed by a customs officer and subject to the provisions of the act of February 13, 1911, as amended (sec. 5, 36 Stat. 901, as amended (19 U.S.C. 267)), shall be calculated as provided in that act.

(2) The charge for the services of the analyst, which shall include administrative and laboratory support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-12/4 employee.

(3) The rate per hour equal to 266 percent of the equivalent hourly rate

of regular pay of the supervising officer (GS-11/4) and the analyst (GS-12/4) is computed as follows:

	Hours
Gross number of working hours in 52 40-hour weeks	2,080
Less:	
Nine legal public holidays—New Years Day, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day	72
Annual Leave—26 days	208
Sick Leave—13 days	104
Total	384
Net number of working hours	1,696
Gross number of working hours in 52 40-hour weeks	2,080
Working hour equivalent of Government contributions for employee retirement, life insurance, and health benefits computed at 8½% of annual rate of pay of employee	176
Equivalent annual working hours	2,256
Support required to equal to 1 man-year	2,256
Equivalent gross annual working hours charged to Food and Drug appropriation	4,512

NOTE: Ratio of equivalent gross annual number of working hours charged to Food and Drug appropriation to net number of annual working hours (4512/1696)=266 pct.

(d) The minimum charge for services of supervising officers shall be not less than the charge for 1 hour and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than one-half hour.

(Sec. 360, 82 Stat. 1175-1176, 1181-1182 (42 U.S.C. 263h))

[38 FR 28630, Oct. 15, 1973, as amended at 42 FR 55207, Oct. 14, 1977; 42 FR 62130, Dec. 9, 1977]

§ 1005.25 Service of process on manufacturers.

(a) Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer's agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 360(d) of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263h(d)) and this section. The agent may be an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

(b) The designation shall be addressed to the Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20857. It shall be in writing and dated; all signatures shall be in ink. The designation shall be made in the legal form required to make it valid and binding on the manufacturer under the laws, corporate bylaws, or other requirements governing the making of the designation by the manufacturer at the place and time where it is made, and the persons or person signing the designation shall certify that it is so made. The designation shall disclose the manufacturer's full legal name and the name(s) under which he conducts his business, if applicable, his principal place of business, and mailing address. If any of the products of the manufacturer do not bear his legal name, the designation shall identify the marks, trade names, or other designations of origin which these products bear. The designation shall provide that it will remain in effect until withdrawn or replaced by the manufacturer and shall bear a declaration of acceptance duly signed by the designated agent. The full legal name and mailing address of the agent shall be stated. Until rejected by the Secretary, designations are binding on the manufacturer even when not in compliance with all the requirements of this section. The designated agent may not assign performance of his function under the designation to another.

(c) Service of any process, notice, order, requirement, or decision specified in section 360(d) of the Radiation Control for Health and Safety Act of 1968 may be made by registered or certified mail addressed to the agent with return receipt requested, or in any other manner authorized by law. In the absence of such a designation or if for any reason service on the designated agent cannot be effected, service may be made as provided in section 360(d) by posting such process, notice, order, requirement, or decision in the Office of the Director, Bureau of Radiological Health and publishing a notice that such service was made in the FEDERAL REGISTER.

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

Subpart A—General Provisions

Sec.
1010.1 Scope.
1010.2 Certification.
1010.3 Identification.
1010.4 Variances.
1010.5 Exemptions for products intended for United States Government use.

Subpart B—Alternate Test Procedures

1010.13 Special test procedures.

Subpart C—Exportation of Electronic Products

1010.20 Electronic products intended for export.

AUTHORITY: Sec. 358, 82 Stat. 1177; 42 U.S.C. 263f, unless otherwise noted.

SOURCE: 38 FR 28631, Oct. 15, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 1010.1 Scope.

The standards listed in this subchapter are prescribed pursuant to section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f) and are applicable to electronic products as specified herein, to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined necessary for the protection of the public health and safety.

[40 FR 32257, July 31, 1975]

§ 1010.2 Certification.

(a) Every manufacturer of an electronic product for which an applicable standard is in effect under this subchapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under this subchapter.

(b) The certification shall be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use, unless the applicable standard prescribes some other manner of certification. All such labels or tags shall be in the English language.

(c) Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Director, Bureau of Radiological Health may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this subchapter.

(d) In the case of products for which it is not feasible to certify in accordance with paragraph (b) of this section, upon application by the manufacturer, the Director, Bureau of Radiological Health may approve an alternate means by which such certification may be provided.

[38 FR 28631, Oct. 15, 1973, as amended at 40 FR 32257, July 31, 1975; 42 FR 18063, Apr. 5, 1977]

§ 1010.3 Identification.

(a) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall set forth the information specified in paragraphs (a)(1) and (2) of this section. This information shall be provided in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the applicable standard. Except for foreign equivalent abbreviations as authorized in paragraph (a)(1) of this section all such labels or tags shall be in the English language.

(1) The full name and address of the manufacturer of the product; abbreviations such as "Co.," "Inc.," or their foreign equivalents and the first and middle initials of individuals may be

used. Where products are sold under a name other than that of the manufacturer of the product, the full name and address of the individual or company under whose name the product was sold may be set forth, provided such individual or company has previously suppled the Director, Bureau of Radiological Health with sufficient information to identify the manufacturer of the product.

(2) The place and month and year of manufacture:

(i) The place of manufacture may be expressed in code provided the manufacturer has previously supplied the Director, Bureau of Radiological Health with the key to such code.

(ii) The month and year of manufacture shall be provided clearly and legibly, without abbreviation, and with the year shown as a four-digit number as follows:

MANUFACTURED: (INSERT MONTH AND YEAR OF MANUFACTURE.)

(b) In the case of products for which it is not feasible to affix identification labeling in accordance with paragraph (a) of this section, upon application by the manufacturer, the Director, Bureau of Radiological Health may approve an alternate means by which such identification may be provided.

(c) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall provide to the Director, Bureau of Radiological Health, a list identifying each brand name which is applied to the product together with the full name and address of the individual or company for whom each product so branded is manufactured.

[40 FR 32257, July 31, 1975, as amended at 42 FR 18063, Apr. 5, 1977]

§ 1010.4 Variances.

(a) *Criteria for variances.* Upon application by a manufacturer (including assembler), the Director, Bureau of Radiological Health, Food and Drug Administration, may grant a variance from one or more provisions of any standard under Subchapter J of this chapter for an electronic product subject to such standard, when he determines that the variance is so limited in its applicability as not to justify an amendment to the standard, or is of such need as not to allow sufficient time for the processing of an amendment to the standard, and that the granting of such variance is in keeping with the purposes of the Radiation Control for Health and Safety Act of 1968. In addition, the issuance of the variance will be based upon a determination that the product:

(1) Utilizes alternate means for providing radiation safety or protection equal to or greater than that provided by products meeting all requirements of the applicable standard, or

(2) Utilizes suitable means for providing radiation safety or protection and is required to perform a necessary function or is intended for a special purpose which cannot be performed or accomplished with equipment meeting all requirements of the applicable standard, or for which one or more requirements of the applicable standard would not be appropriate.

(b) *Applications for variances.* Applications for variances or for amendments or extensions thereof shall be submitted in an original and two copies to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

(1) The application for variance shall include the following information:

(i) A description of the product and its intended use.

(ii) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use.

(iii) A description of the manner in which it is proposed to deviate from the requirements of the applicable standard.

(iv) A description of the advantages to be derived from such deviation.

(v) An explanation of how alternate or suitable means of radiation protection will be provided.

(vi) The period of time it is desired that the variance be in effect, and, if appropriate, the number of units the applicant wishes to manufacture.

(vii) In the case of prototype or experimental equipment, the proposed location of each unit.

(viii) Such other information required by regulation or by the Director, Bureau of Radiological Health, to evaluate and act on the application.

(ix) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(x) [Reserved]

(xi) If the electronic product is used in a clinical investigation involving human subjects, is subject to the requirements for institutional review set forth in Part 56 of this chapter, and is subject to the requirements for informed consent set forth in Part 50 of this chapter, the investigation shall be conducted in compliance with such requirements.

(2) The application for amendment or extension of a variance shall include the following information:

(i) The variance number and expiration date.

(ii) The amendment or extension requested and basis for the amendment or extension.

(iii) A description of the effect of the amendment or extension on protection from radiation produced by the product.

(iv) An explanation of how alternate or suitable means of protection will be provided.

(c) *Ruling on applications.* (1) The director, Bureau of Radiological Health, may approve or deny, in whole or in part, a requested variance or any amendment or extension thereof, and the director shall inform the applicant in writing of this action on a requested variance or amendment or extension. The written notice will state the manner in which the variance differs from the standard, the effective date and the termination date of the variance, a summary of the requirements and conditions attached to the variance, any other information that may be relevant to the application or variance, and, if appropriate, the number of units or other similar limitations for which the variance is approved. Each variance will be assigned an identifying number.

(2) A notice of availability of an approved variance or any amendment or extension thereof will be published in the FEDERAL REGISTER. The notice will state the name of the applicant, the identifying number, the effective date and the termination date of the variance, the product for which the variance is approved, and the specific requirements of the applicable standard from which the variance is approved.

(3) The director, Bureau of Radiological Health, shall amend or withdraw a variance whenever the Director determines that this action is necessary to protect the public health or otherwise is justified by this subchapter. Such action will become effective on the date specified in the written notice of the action sent to the applicant, except that it will become effective immediately upon notification to the applicant when the Director determines that such action is necessary to prevent an imminent health hazard.

(4) All applications for variances and for amendments and extensions thereof and all correspondence (including written notices of approval) on these applications will be available for public disclosure in the office of the Dockets Management Branch, except for information regarded as confidential under section 360A(e) of the act.

(d) *Certification of equipment covered by variance.* The manufacturer of any product for which a variance is granted shall modify the tag, label, or other certification required by § 1010.2 to state:

(1) That the product is in conformity with the applicable standard, except with respect to those characteristics covered by the variance;

(2) That the product is in conformity with the provisions of the variance; and

(3) The assigned number and effective date of the variance.

(Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 601, 701(a), 706, and 801, 52 Stat. 1049-1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360l); secs. 215, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended; (42 U.S.C. 216, 262, 263b-263n) secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 701(a), 706, and 801, 52 Stat. 1049-1053 as amended, 1055, 1058 as amended, 55 Stat 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-407 as amended, 76 Stat. 794-795 as amended, 90 Stat. 540-560, 562-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 371(a), 376 and 381); secs. 215, 301, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 241, 262, 263b-263n))

[39 FR 13879, Apr. 18, 1974, as amended at 44 FR 48191, Aug. 17, 1979; 50 FR 7518, Feb. 22, 1985; 50 FR 13565, Apr. 5, 1985]

§ 1010.5 Exemptions for products intended for United States Government use.

(a) *Criteria for exemption.* Upon application by a manufacturer (including assembler) or by a United States department or agency, the Director, Bureau of Radiological Health, food and Drug Administration, may grant an exemption from any performance standard under Subchapter J of this chapter for an electronic product, or class of products, otherwise subject to such standard when he determines that such electronic product or class is intended for use by departments or agencies of the United States and meets the criteria set forth in paragraph (a) (1) or (2) of this section.

(1) The procuring agency shall prescribe procurement specifications for the product or class of products governing emissions of electronic product radiation, and the product or class shall be of a type used solely or predominantly by a department or agency of the United States.

(2) The product or class of products is intended for research, investigations, studies, demonstration, or training, or for reasons of national security.

(b) *Consultation between the procuring agency and the Food and Drug Administration.* The United States department or agency that intends to procure or manufacture a product or class of products subject to electronic product radiation safety standards contained in this subchapter should consult with the Bureau of Radiological Health, Food and Drug Administration, whenever it is anticipated that the specifications for the product or class must deviate from, or be in conflict with, such applicable standards. Such consultation should occur as early as possible during development of such specifications. The department or agency should include in the specifications all requirements of such standards that are not in conflict with, or are not inappropriate for, the special or unique uses for which the product is intended. The procuring agency should indicate to the Bureau of Radiological Health if it desires to be notified of the approval, amendment, or withdrawal of the exemption.

(c) *Application for exemption.* An original and two copies of any application for exemption, or for amendment or extension thereof, shall be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. For an exemption pursuant to the criteria prescribed in paragraph (a)(1) of this section, the application shall include the information prescribed in paragraphs (c)(1) through (13) of this section. For an exemption pursuant to the criteria prescribed in paragraph (a)(2) of this section, the application shall include the information prescribed in paragraphs (c)(3) through (13) of this section. An application for exemption, or for amendment or extension thereof, and correspondence relating to such application shall be made available for public disclosure in the Dockets Management Branch except for confidential or proprietary information submitted in accordance with Part 20 of this chapter. Information classified for reasons of national security shall not be included in the application. Except as indicated above, the application for exemption shall include the following:

(1) The procurement specifications for the product or class of products that govern emissions of electronic product radiation.

(2) Evidence that the product or class of products is of a type used solely or predominantly by depart-

ments or agencies of the United States.

(3) Evidence that such product or class of products is intended for use by a department or agency of the United States.

(4) A description of the product or class of products and its intended use.

(5) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use.

(6) A description of the manner in which it is proposed that the product or class of products shall deviate from the requirements of the applicable standard.

(7) An explanation of the advantages to be derived from such deviation.

(8) An explanation of how means of radiation protection will be provided where the product or class of products deviates from the requirements of the applicable standard.

(9) The period of time it is desired that the exemption be in effect, and, if appropriate, the number of units to be manufactured under the exemption.

(10) The name, address, and telephone number of the manufacturer or his agent.

(11) The name, address, and telephone number of the appropriate office of the United States department or agency purchasing the product or class of products.

(12) Such other information required by regulation or by the Director, Bureau of Radiological Health, to evaluate and act on the application. Where such information includes nonclinical laboratory studies, the information shall include, with respect to each nonclinical study, either a statement that each study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations. When such information includes clinical investigations involving human subjects, the information shall include, with respect to each clinical investigation, either a statement that each investigation was conducted in compliance with the requirements set forth in Part 56 of this chapter, or a statement that the investigation is not subject to such requirements in accordance with § 56.104 or § 56.105 and a statement that each investigation was conducted in compliance with the requirements set forth in Part 50 of this chapter.

(13) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) *Amendment or extension of an exemption.* An exemption is granted on the basis of the information contained in the orginal applicaion. Therefore, if changes are needed in the radiation safety specifications for the product, or its use, or related radiation control procedures such that the information in the original application would no longer be correct with respect to radiation safety, the applicant shall submit in advance of such changes a request for an amendment to the exemption. He also shall submit a request for extension of the exemption, if needed, at least 60 days before the expiration date. The application for amendment or extension of an exemption shall include the following information:

(1) The exemption number and expiration date.

(2) The amendment or extension requested and basis for the amendment or extension.

(3) If the radiation safety specifications for the product or class of products or the product's or class of products' use or related radiation control procedures differ from the description provided in the original application, a description of such changes.

(e) *Ruling on an application.* (1) The Director, Bureau of Radiological Health, may grant an exemption including in the written notice of exemption such conditions or terms as may be necessary to protect the public health and safety and shall notify the applicant in writing of his action. The conditions or terms of the exemption may include specifications concerning the manufacture, use, control, and disposal of the excess or surplus exempted product of class of products as provided in the Code of Federal Regulations, Title 41, Subtitle C. Each exemption will be assigned an identifying number.

(2) The Director, Bureau of Radiological Health, shall amend or withdraw an exemption whenever he determines that such action is necessary to protect the public health or otherwise is justified by provisions of the act or this subchapter. Such action shall become effective on the date specified in the written notice of the action sent to the applicant, except that it shall become effective immediately when the Director determines that it is necessary to prevent an imminent health hazard.

(f) *Identification of equipment covered by exemption.* The manufacturer of any product for which an exemption is granted shall provide the following identification in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the exemption:

CAUTION

This electronic product has been exempted from Food and Drug Administration radiation safety performance standards prescribed in the Code of Federal Regulations, Title 21, Chapter I, Subchapter J, pursuant to Exemption No.——, granted on ————

(Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 601, 701(a), 706, and 801, 52 Stat. 1049-1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360i); secs. 215, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended; (42 U.S.C. 216, 262, 263b-263n))

[42 FR 44229, Sept. 2, 1977; 42 FR 61257, Dec. 2, 1977, as amended at 44 FR 17657, Mar. 23, 1979; 46 FR 8460, 8958, Jan. 27, 1981; 50 FR 7518, Feb. 22, 1985; 50 FR 13564, Apr. 5, 1985]

Subpart B—Alternate Test Procedures

§ 1010.13 Special test procedures.

The Director, Bureau of Radiological Health may, on the basis of a written application by a manufacturer, authorize test programs other than those set forth in the standards under this subchapter for an electronic product if he determines that such products are not susceptible to satisfactory testing by the procedures set forth in the standard and that the alternative test procedures assure compliance with the standard.

[40 FR 32257, July 31, 1975]

Subpart C—Exportation of Electronic Products

§ 1010.20 Electronic products intended for export.

The performance standards prescribed in this subchapter shall not apply to any electronic product which is intended solely for export if:

(a) Such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and

(b) Such product meets all the applicable requirements of the country to which such product is intended for export.

[40 FR 32257, July 31, 1975]

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

Sec.

1020.10 Television receivers.
1020.20 Cold-cathode gas discharge tubes.
1020.30 Diagnostic x-ray systems and their major components.
1020.31 Radiographic equipment.
1020.32 Fluoroscopic equipment.
1020.33 Computed tomography (CT) equipment.
1020.40 Cabinet x-ray systems.

AUTHORITY: Sec. 358, 82 Stat. 1177-1179; 42 U.S.C. 263f.

SOURCE: 38 FR 28632, Oct. 15, 1973, unless otherwise noted.

§ 1020.10 Television receivers.

(a) *Applicability.* The provisions of this section are applicable to television receivers manufactured subsequent to January 15, 1970.

(b) *Definitions.* (1) "External surface" means the cabinet or enclosure provided by the manufacturer as part of the receiver. If a cabinet or enclosure is not provided as part of the receiver, the external surface shall be considered to be a hypothetical cabinet, the plane surfaces of which are located at those minimum distances from the chassis sufficient to enclose all components of the receiver except that portion of the neck and socket of the cathode-ray tube which normally extends beyond the plane surfaces of the enclosure.

(2) "Maximum test voltage" means 130 root mean square volts if the receiver is designed to operate from nominal 110 to 120 root mean square volt power sources. If the receiver is designed to operate from a power source having some voltage other than from nominal 110 to 120 root mean square volts, maximum test voltage means 110 percent of the nominal root mean square voltage specified by the manufacturer for the power source.

(3) "Service controls" means all of those controls on a television receiver provided by the manufacturer for purposes of adjustment which, under normal usage, are not accessible to the user.

(4) "Television receiver" means an electronic product designed to receive and display a television picture through broadcast, cable, or closed circuit television.

(5) "Usable picture" means a picture in synchronization and transmitting viewable intelligence.

(6) "User controls" means all of those controls on a television receiver, provided by the manufacturer for purposes of adjustment, which on a fully assembled receiver under normal usage, are accessible to the user.

(c) *Requirements*—(1)*Exposure rate limit.* Radiation exposure rates produced by a television receiver shall not exceed 0.5 milliroentgens per hour at a distance of five (5) centimeters from any point on the external surface of the receiver, as measured in accordance with this section.

(2) *Measurements.* Compliance with the exposure rate limit defined in paragraph (c)(1) of this section shall be determined by measurements made with an instrument, the radiation sensitive volume of which shall have a cross section parallel to the external surface of the receiver with an area of ten (10) square centimeters and no dimension larger than five (5) centimeters. Measurements made with instruments having other areas must be corrected for spatial nonuniformity of the radiation field to obtain the exposure rate average over a ten (10) square centimeter area.

(3) *Test conditions.* All measurements shall be made with the receiver displaying a usable picture and with the power source operated at supply voltages up to the maximum test voltage of the receiver and, as applicable, under the following specific conditions:

(i) On television receivers manufactured subsequent to January 15, 1970, measurements shall be made with all user controls adjusted so as to produce maximum x-radiation emissions from the receiver.

(ii) On television receivers manufactured subsequent to June 1, 1970, measurements shall be made with all user controls and all service controls adjusted to combinations which result in the production of maximum x-radiation emissions.

(iii) On television receivers manufactured subsequent to June 1, 1971, measurements shall be made under the conditions described in paragraph (c)(3) (ii) of this section, together with conditions identical to those which result from that component or circuit failure which maximizes x-radiation emissions.

(4) *Critical component warning.* The manufacturer shall permanently affix or inscribe a warning label, clearly legible under conditions of service, on all television receivers which could produce radiation exposure rates in excess of the requirements of this section as a result of failure or improper adjustment or improper replacement of a circuit or shield component. The warning label shall include the specifi-

cation of operating high voltage and an instruction for adjusting the high voltage to the specified value.

§ 1020.20 Cold-cathode gas discharge tubes.

(a) *Applicability.* The provisions of this section are applicable to cold-cathode gas discharge tubes designed to demonstrate the effects of a flow of electrons or the production of x-radiation as specified herein.

(b) *Definitions.* "Beam blocking device" means a movable or removable portion of any enclosure around a cold-cathode gas discharge tube, which may be opened or closed to permit or prevent the emergence of an exit beam.

"Cold-cathode gas discharge tube" means an electronic device in which electron flow is produced and sustained by ionization of contained gas atoms and ion bombardment of the cathode.

"Exit beam" means that portion of the radiation which passes through the aperture resulting from the opening of the beam blocking device.

"Exposure" means the sum of the electrical charges on all of the ions of one sign produced in air when all electrons liberated by photons in a volume element of air are completely stopped in air divided by the mass of the air in the volume element. The special unit of exposure is the roentgen. One (1) roentgen equals 2.58×10^{-4} coulombs/kilogram.

(c) *Requirements*—(1) *Exposure rate limit.* (i) Radiation exposure rates produced by cold-cathode gas discharge tubes shall not exceed 10 mR./hr. at a distance of thirty (30) centimeters from any point on the external surface of the tube, as measured in accordance with this section.

(ii) The divergence of the exit beam from tubes designed primarily to demonstrate the effects of x radiation, with the beam blocking device in the open position, shall not exceed (Pi) steradians.

(2) *Measurements.* (i) Compliance with the exposure rate limit defined in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over an area of one hundred (100) square centimeters with no linear dimension greater than twenty (20) centimeters.

(ii) Measurements of exposure rates from tubes in enclosures from which the tubes cannot be removed without destroying the function of the tube may be made at a distance of thirty (30) centimeters from any point on the external surface of the enclosure, provided:

(*a*) In the case of enclosures containing tubes designed primarily to demonstrate the production of x radiation, measurements shall be made with any beam blocking device in the beam blocking position, or

(*b*) In the case of enclosures containing tubes designed primarily to demonstrate the effects of a flow of electrons, measurements shall be made with all movable or removable parts of such enclosure in the position which would maximize external exposure levels.

(3) *Test conditions.* (i) Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer.

(ii) Measurements shall be made with the tube operated under forward and reverse polarity.

(4) *Instructions, labels, and warnings.* (i) Manufacturers shall provide, or cause to be provided, with each tube to which this section is applicable, appropriate safety instructions, together with instructions for the use of such tube, including the specification of a power source for use with the tube.

(ii) Each enclosure or tube shall have inscribed on or permanently affixed to it, tags or labels, which identify the intended polarity of the terminals and:

(*a*) In the case of tubes designed primarily to demonstrate the heat effect, fluorescence effect, or magnetic effect, a warning that application of power in excess of that specified may result in the production of x-rays in excess of allowable limits; and (*b*) in the case of tubes designed primarily to demonstrate the production of x-radiation, a warning that this device produces x-rays when energized.

(iii) The tag or label required by this paragraph shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

§ 1020.30 Diagnostic x-ray systems and their major components.

(a) *Applicability.* (1) The provisions of this section are applicable to:

(i) The following components of diagnostic x-ray systems:

(*a*) Tube housing assemblies, x-ray controls, x-ray high-voltage generators, tables, cradles, film changers, vertical cassette holders mounted in a fixed location and cassette holders with front panels, and beam-limiting devices manufactured after August 1, 1974.

(*b*) Fluoroscopic imaging assemblies manufactured after August 1, 1974 and before April 26, 1977.

(*c*) Spot-film devices and image intensifiers manufactured after April 26, 1977.

(*d*) Cephalometric devices manufactured after February 25, 1978.

(*e*) Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978.

(ii) Diagnostic x-ray systems, except computed tomography x-ray systems, incorporating one or more of such components; however, such x-ray systems shall be required to comply only with those provisions of this section and §§ 1020.31 and 1020.32 which relate to the components certified in accordance with paragraph (c) of this section and installed into the systems.

(iii) Computed tomography x-rays systems manufactured before November 29, 1984.

(2) The following provisions of this section and § 1020.33 are applicable to computed tomography x-ray systems manufactured or remanufactured on and after November 29, 1984:

(i) Section 1020.30(a);

(ii) Section 1020.30(b)(36) (iii)–(v);

(iii) Section 1020.30(b) (58)–(62);

(iv) Section 1020.30(h)(3) (vi)–(viii);

(v) Section 1020.30(n);

(vi) Section 1020.33 (a) and (b);

(vii) Section 1020.33(c)(1) as it affects § 1020.33(c)(2); and

(viii) Section 1020.33(c)(2).

(3) The provisions of this section and § 1020.33 in its entirety, including those provisions in paragraph (a)(2) of this section, are applicable to computed tomography x-ray systems manufactured or remanufactured on and after September 3, 1985.

(b) *Definitions.* As used in this section and §§ 1020.31, 1020.32, and 1020.33, the following definitions apply:

(1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

(2) "Aluminum equivalent" means the thickness of aluminum (type 1100 alloy)[1] affording the same attenuation, under specified conditions, as the material in question.

(3) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

(4) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation.

(5) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

(6) "Beam axis" means a line from the source through the centers of the x-ray fields.

(7) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

(8) "Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

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[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper, as given in "Aluminum Standards and Data" (1969). Copies may be otained from: The Aluminum Association, New York, NY.

$$C=\frac{s}{\bar{X}}=\frac{1}{\bar{X}}\left[\sum_{i=1}^{n}\frac{(X_i-\bar{X})^2}{n-1}\right]^{\frac{1}{2}}$$

where

s = Estimated standard deviation of the population.
$\bar{X}$ = Mean value of observations in sample.
X_i = ith observation sampled.
n = Number of observations sampled.

(9) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

(10) "Cooling curve" means the graphical relationship between heat units stored and cooling time.

(11) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

(12) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

(13) "Equipment" means x-ray equipment.

(14) "Exposure" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.

(15) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(16) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

(17) "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

(18) "Half-value layer, HVL" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(19) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect portions of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

(20) "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(i) The useful beam; and

(ii) Radiation produced when the exposure switch or timer is not activated.

(21) "Leakage technique factors" means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(i) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mAs) or the minimum obtainable from the unit, whichever is larger.

(ii) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

(iii) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

(22) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and in-

cluding the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

(23) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

Percent line-voltage regulation

$$\frac{100(V_n - V_l)}{V_l}$$

where

V_n = No-load line potential and
V_l = Load line potential.

(24) "Maximum line current" means the rms current in the supply line of an x-ray machine operating at its maximum rating.

(25) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(26) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

(27) "Rated line voltage" means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

(28) "Rated output current" means the maximum allowable load current of the x-ray high-voltage generator.

(29) "Rated output voltage" means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.

(30) "Rating" means the operating limits specified by the manufacturer.

(31) "Recording" means producing a permanent form of an image resulting from x-ray photons (e.g., film, video tape).

(32) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

(33) "Source" means the focal spot of the x-ray tube.

(34) "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.

(35) "Stationary equipment" means equipment which is installed in a fixed location.

(36) "Technique factors" means the following conditions of operation:

(i) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(ii) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.

(iii) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs.

(iv) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent.

(v) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

(37) "Tube" means an x-ray tube, unless otherwise specified.

(38) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

(39) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(40) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

(41) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless

adjustment of the x-ray field size at a given SID.

(42) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

(43) "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

(44) "X-ray equipment" means an x-ray system, subsystem, or component thereof.

(45) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(46) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

(47) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

(48) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this section and §§ 1020.31 and 1020.32.

(49) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(50) "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

(51) "Spot-film device" means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

(52) "Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

(53) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

(54) "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

(55) "Cassette holder" means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film cassette during an x-ray exposure.

(56) "Quick change x-ray tube" means an x-ray tube designed for use in its associated tube housing such that:

(i) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of paragraphs (k) and (m) of this section, and

(ii) The focal spot position will not cause noncompliance with the provisions of this section or § 1020.31 or § 1020.32, and

(iii) The shielding within the tube housing cannot be displaced, and

(iv) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube housing will not result in noncompliance of the x-ray system with the applicable field limitation and alignment requirements of §§ 1020.31 and 1020.32.

(57) "Accessory component" means:

(i) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this subchapter but which requires an initial determination of compatibility with the system, or

(ii) A component necessary for compliance of the system with applicable provisions of this subchapter but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices, or

(iii) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

(58) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

(59) "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

(60) "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

(61) "Tomogram" means the depiction of the x-ray attenuation properties of a section through a body.

(62) "Dose" means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm where de is the mean energy imparted by ionizing radiation to matter of mass dm.

(c) *Certification of components.* Each component subject to this section and §§ 1020.31, 1020.32, and 1020.33, shall be certified by the manufacturer thereof as a product which meets all applicable standards in accordance with the provisions of § 1010.2 of this chapter. Where a combination of two or more such components is manufactured, marketed, and delivered as a system or subsystem, its certification may be applicable to all components contained therein, if authorized in writing by the Director or Deputy Director of the Bureau of Radiological Health, or the Director, Division of Compliance of that Bureau upon application by the manufacturer. Certification that the product conforms to all applicable standards under this part shall be construed to mean that the component, system, or subsystem can meet the applicable provisions of this section and §§ 1020.31, 1020.32, and 1020.33, if installed in a diagnostic x-ray system in accordance with instructions.

(d) *Certification by assembler.* An assembler who installs one or more components certified as required by paragraph (c) of this section into an x-ray system shall install certified components that are of the type required by § 1020.31, § 1020.32 or § 1020.33, and, except as provided for in paragraph (d)(2) of this section, shall assemble, install, adjust, and test the certified components in accordance with the instructions of their respective manufacturers. All assemblers who install certified components shall file a report of such assembly as specified in paragraphs (d)(1), (2), and (3) of this section. The report will be construed as the assembler's certification and identification under §§ 1010.2 and 1010.3 of this chapter. All assembler reports must be on a form prescribed by and available from the Director, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20857. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(1) *Reporting compliance.* An assembler who installs one or more certified components into an x-ray system or subsystem, having properly followed the assembly instructions provided him by the component manufacturer, shall certify to this by filing a report containing the information prescribed on the form which shall include the following:

(i) The full name and address of the assembler and the date of assembly or installation.

(ii) The name and address of the purchaser and the location and specific identification of the x-ray system or subsystem.

(iii) An affirmation that all instruction manuals and other information as required by paragraph (h) of this section applicable to the newly installed x-ray equipment have been delivered to the purchaser.

(iv) A statement of the type and intended use of the x-ray system or subsystem into which the certified components were assembled or installed, such as "radiographic—stationary general purpose."

(v) A list of all certified components which were assembled or installed by him into the x-ray system or subsystem in accordance with the instructions of the component manufacturers, identifying the components by type, manufacturer, model number, and serial number.

(vi) An affirmation that the certified components listed pursuant to paragraph (d)(2)(v) of this section were assembled according to the instructions provided by the manufacturer(s) of such components.

(vii) An affirmation that all certified components installed in the x-ray system or subsystem were of the type required by § 1020.31, § 1020.32, or § 1020.33.

(viii) An affirmation that a copy of this report will be transmitted to the purchaser and, where applicable, to the State agency responsible for radiation protection, in accordance with the requirements of this paragraph.

(2) *Reporting noncompatibility.* An assembler who installs a certified component into an x-ray system shall file a report indicating noncompatibility if he is unable to follow the instructions of the manufacturer of such certified component, provided other component(s) of the system do not meet the manufacturer's specifications for compatibility as given by the certified component manufacturer pursuant to paragraph (g) of this section and provided there is no commercially available certified component of a similar type which is compatible with the x-ray system. In addition, the component(s) of the system not meeting the specification for compatibility must either be of a type listed in paragraph (a)(1) of this section which does not bear a certification label due to date of manufacture, or if it is a component not of the type listed in paragraph (a)(1) of this section, it must have been purchased as new prior to August 1, 1974. No assembler shall perform any modification of a certified component which will adversely affect the performance of the certified component with respect to the requirements of this section and §§ 1020.31, 1020.32 and 1020.33. The assembler shall file a report indicating noncompatibility containing information prescribed on the form which shall include the following:

(i) The full name and address of the assembler and the date of assembly or installation.

(ii) The name and address of the purchaser and the location and specific identification of the x-ray system or subsystem.

(iii) An affirmation that all instruction manuals and other information as required by paragraph (h) of this section applicable to the newly installed x-ray equipment have been delivered to the purchaser.

(iv) A statement of the type or intended use of the x-ray system or subsystem into which the certified components were assembled or installed, such as "radiographic—stationary general purpose."

(v) A list of all certified component(s) which were assembled or installed by him into the x-ray system or subsystem and which could not be assembled, installed, adjusted, and tested in accordance with the manufacturer's instructions due to reasons specified in this paragraph (this paragraph (d)(2)), identifying the components by type, manufacturer, model number, and serial number.

(vi) An affirmation that the certified component(s) listed pursuant to paragraph (d)(2)(v) of this section could not be assembled, installed, adjusted, and tested in accordance with the installation instructions of their respective manufacturers due to reasons specified in this paragraph (this paragraph (d)(2)), and that no certified component was modified so as to adversely affect its performance with respect to the requirements of this section and §§ 1020.31, 1020.32 and 1020.33.

(vii) For each certified component listed pursuant to paragraph (d)(2)(v) of this section, a full and complete explanation of why the manufacturer's installation instructions could not be followed in performing the assembly, including a listing by type, manufacturer, and model number of the incompatible component(s) already in the system, and either evidence of its date of purchase as new if it is not a type of component listed in paragraph (a)(1) of this section, or if it is a type of component listed in paragraph (a)(1) of this section, a statement that it did not bear a certification label due to its date of manufacture.

(viii) An affirmation that all certified components installed in the x-ray system or subsystem were of the type required by § 1020.31, § 1020.32 or 1020.33.

(ix) An affirmation that a copy of this report will be transmitted to the purchaser and, where applicable, to the State agency responsible for radiation protection, in accordance with the requirements of this paragraph.

(3) *Accessory components.* The following requirements apply to the assembly of accessory certified components and x-ray systems that do not require assembly by the dealer or purchaser.

(i) The initial installation or assembly of interchangeable and removable accessory certified components within a diagnostic x-ray system following delivery at the user's facility shall be reported as required by paragraphs (d)(1) and (2) of this section. No report of assembly is required for subsequent use of such components.

(ii) Assembler certification as specified in paragraphs (d)(1) and (2) of this section is not required for certified components or systems that have been described by their manufacturer in the information furnished the user as not requiring assembler certification. Prior to stating that assembler certification is not required for a component or system, the manufacturer of the item must have reported to the Bureau of Radiological Health, in the report required by § 1002.10 of this chapter, that compliance with this section and §§ 1020.31, 1020.32 and 1020.33 is assured by the existence of the following conditions:

(*a*) Certification of compliance by the manufacturer is not contingent upon acts of assembly or installation by the dealer or purchaser.

(*b*) Preparation for use by either the dealer or user does not require adherence to the manufacturer's instructions to ensure compliance.

(*c*) Interconnection or use, or both, of the component or systems does not require compatibility specifications.

(e) *Identification of x-ray components.* In addition to the identification requirements specified in § 1010.3 of this chapter, manufacturers of components subject to this section and §§ 1020.31, 1020.32 and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices which are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product, so as to be legible and accessible to view. Where the certification of a system or subsystem, consisting of two or more components, has been authorized pursuant to paragraph (c) of this section, a single inscription, tag, or label bearing such information may be used to identify the product.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube-housing assembly certified pursuant to paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels that are no longer applicable.

(3) *Quick-change x-ray tubes.* The requirements of paragraph (e)(2) of this section shall not apply to tube-housing assemblies designed and designated by

their original manufacturer to contain quick-change x-ray tubes. The manufacturer of such x-ray tubes shall include with each replacement tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube-housing assembly and to remove the cover or deface the previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.

(f) *Limits of responsibility*—(1) *Manufacturer.* The manufacturer of a certified component installed or assembled into an x-ray system or subsystem by another person shall not be liable for the noncompliance of such component which is attributable solely to the improper installation or assembly of the component into the system, but shall be held responsible for noncompliance if improper assembly was a result of inadequate instructions provided by such component manufacturer.

(2) *Assembler.* The person who certified as to the assembly of an x-ray system or subsystem shall not be liable for noncompliance of a certified component if such assembly is in accordance with the instructions provided by the manufacturer of the component, but shall be held responsible for noncompliance of a component which is attributable solely to improper assembly or installation into the system or subsystem.

(g) *Information to be provided to assemblers.* Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§ 1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible.

(h) *Information to be provided for users.* Manufacturers of x-ray equipment shall provide for purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) *All x-ray equipment.* For x-ray equipment to which this section and §§ 1020.31, 1020.32, and 1020.33 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§ 1020.31, 1020.32, and 1020.33.

(2) *Tube housing assemblies.* For each tube housing assembly, there shall be provided:

(i) Statements of the leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the tube housing assembly manufacturer states compatibility, the minimum filtration permanently in the useful beam expressed as millimeters of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) Tube rating charts.

If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self-rectified, single-phase half-wave rectified, single-phase full-wave rectified, three-phase six pulse, three-phase 12 pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators.* For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, he shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(s);

(iii) A statement of the technique factors that constitute the maximum line current condition described in paragraph (h)(3)(ii) of this section;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the preindication given by labeled technique factor control settings or indicators during any radiographic or CT exposure where the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated;

(vii) A statement of the maximum deviation from the continuous indication of x-ray tube potential and current during any fluoroscopic exposure when the equipment is connected to a power supply as described in accordance with this paragraph; and

(viii) A statement describing the measurement criteria for all technique factors used in paragraphs (h)(3) (iii), (vi), and (vii) of this section; for example, the beginning and end points of exposure time measured with respect to a certain percentage of the voltage waveform.

(4) *Beam-limiting device.* For each variable-aperture beam-limiting device, there shall be provided:

(i) Leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the beam-limiting device manufacturer states compatibility; and

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(i) [Reserved]

(j) *Warning label.* The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(k) *Leakage radiation from the diagnostic source assembly.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens in 1 hour when the x-ray tube is operated at the leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(l) *Radiation from components other than the diagnostic source assembly.* The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(m) *Beam quality*—(1) *Half-value layer.* The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in Table I under "Specified dental systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; and under "Other x-ray systems," for all other x-ray systems subject to this section. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made. Positive means[2] shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.

TABLE I

X-ray tube voltage (kilovolt peak)		Minimum HVL (mm of Al)	
Designed operating range	Measured operating potential	Specified dental systems	Other X-ray systems
Below 50	30	1.5	0.3
	40	1.5	0.4
	49	1.5	0.5
50 to 70	50	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(2) *Measuring compliance.* For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.

(n) *Aluminum equivalent of material between patient and image receptor.* Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in Table II, which are used between the patient and image receptor may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has a half-value layer of 2.7 millimeters of aluminum. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids.

TABLE II

Item	Aluminum equivalent (millimeters)
Front panel(s) of cassette holder (total of all)	1.0
Front panel(s) of film changer (total of all)	1.0
Stationary tabletop	1.0
Movable tabletop (including stationary subtop)	1.5
Cradle	2.0
Radiation therapy simulator tabletop	5.0

(o) *Battery charge indicator.* On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(p) *Assembly and reassembly of diagnostic x-ray system.* The following provisions apply to the assembly and reassembly of diagnostic x-ray components specified in paragraph (a)(1) of this section into diagnostic x-ray systems.

(1) *Assembly after August 1, 1974.* Except as provided in paragraph (p)(2)of this section, specified components which are assembled after August 1, 1974 into those x-ray systems which contain, or will contain upon completion of the assembly, one or more components certified pursuant to paragraph (c) of this section, may only be those which have themselves been so certified. For example, after August 1, 1974:

(i) An assembler who installs a new, complete diagnostic x-ray system may not assemble a system consisting of both certified and uncertified components.

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[2] In the case of a system which is to be operated with more than on thickness of filtration, this requirement can be met by a filter interlock with the kilovoltage selector which will prevent x-ray emission if the minimum required filtration is not in place.

(ii) An assembler who installs components into an existing diagnostic x-ray system containing one or more certified components prior to such installation may only install components which have been certified by the component manufacturer(s), regardless of whether certified components themselves are replaced.

(iii) An assembler who installs a group of components into an existing diagnostic x-ray system containing no certified components prior to the assembly may not install a combination of certified and uncertified components but must install either all uncertified components or all certified components into such a system.

(iv) An assembler may reassemble a previously existing (used) system for resale whether or not the system is composed of all uncertified or a combination of certified and uncertified components. However, any components added to or installed in place of original components in an existing system composed of one or more certified components must be certified.

(2) *Purchase prior to August 1, 1974.* The provisions of paragraph (p)(1) of this section do not apply to the assembly of specified components, provided:

(i) All of the specified components which are assembled into the x-ray system after August 1, 1974, were purchased prior to that date and

(ii) The report filed pursuant to paragraph (d) of this section includes adequate evidence that all the specified components assembled were purchased prior to August 1, 1974. A copy of a notarized bill of sale or other notarized contract for purchase clearly establishing the date of purchase of each of the specified components will be considered adequate evidence.

(3)-(4) [Reserved]

(5) *Repair of x-ray systems.* The following requirements govern the assembly and reassembly of diagnostic x-ray components during repair of diagnostic x-ray components and systems:

(i) The removal of a component, whether certified or uncertified, from an x-ray system for the purpose of repair and the subsequent reinstallation of the component into the system following repair are not prohibited by this section. Those performing repair of certified components are not required to recertify the repaired component under paragraph (c) of this section except for reloaded previously certified x-ray tube housing assemblies. A report pursuant to paragraph (d) of this section need not be filed to report the reinstallation of a certified component into an x-ray system following repair of the component or system.

(ii) The installation into an x-ray system of components specified in paragraph (a) of this section on an exchange basis when an identical model is installed in place of a malfunctioning component shall not be subject to paragraph (p)(1) of this section or affect the status of the x-ray system under that paragraph. A report pursuant to paragraph (d) of this section must be filed to report installation of certified components.

(iii) Components installed temporarily in an x-ray system in place of certified components removed temporarily for repair must be certified. The temporary installation of such certified components is not subject to the report required in paragraph (d) of this section, provided the temporarily installed component is identified by a tag or label bearing the information set forth in paragraph (p)(5)(iii) (*a*) or (*b*) of this section. The replacement of the temporarily installed component by a permanently installed certified component must be reported in accordance with paragraph (d) of this section.

(*a*) Temporarily installed compatible component. A temporarily installed compatible component must bear the following statement and information:

TEMPORARILY INSTALLED COMPATIBLE COMPONENT

This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.

Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation

(*b*) Temporarily installed noncompatible component. A temporarily installed noncompatible component must bear the following statement and information:

TEMPORARILY INSTALLED NONCOMPATIBLE COMPONENT

This certified component has been assembled or installed by me, but could not be assembled, installed, adjusted, and tested according to the instructions provided by the manufacturer because other already existing components of the system do not meet the compatibility specifications of the certified component being installed, and there are no commercially available certified components of a similar type that are compatible with the system.

Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation

(6) *Accessory components.* The use with an x-ray system of accessory components specified in paragraph (a) of this section that are not permanently installed in the x-ray system, which are not essential to the performance of the system in compliance with the requirements of this section and §§ 1020.31 1020.32, and 1020.33, and which are subject to the assembler reporting exceptions of paragraph (d)(3) of this section are not subject to paragraph (p)(1) of this section and do not affect the status of the x-ray system under that paragraph.

(q) *Modification of certified diagnostic x-ray components and systems.* (1) Diagnostic x-ray components and systems certified in accordance with § 1010.2 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter unless a variance in accordance with § 1010.4 of this chapter or an exemption under section 358(a)(5) or 360B(b) of the Public Health Service Act has been granted.

(2) The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of § 1020.31 or § 1020.32, or § 1020.33. The owner who causes such modification need not submit the reports required by Subpart B of Part 1002 of this chapter, provided the owner records the date and the details of the modification, and provided the modification of the x-ray system does not result in a failure to comply with § 1020.31, § 1020.32, or § 1020.33.

[38 FR 28632, Oct. 15, 1973, as amended at 39 FR 13880, Apr. 18, 1974; 42 FR 10985, Feb. 25, 1977; 42 FR 44232, Sept. 2, 1977; 44 FR 29654, May 22, 1979; 44 FR 49671, Aug. 24, 1979; 44 FR 68824, Nov. 30, 1979; 45 FR 27928, Apr. 25, 1980; 47 FR 50215, Nov. 5, 1982; 49 FR 34711, Aug. 31, 1984; 50 FR 15544, Apr. 19, 1985]

§ 1020.31 Radiographic equipment.

The provisions of this section apply to equipment for the recording of images, except equipment involving use of an image intensifier or computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Control and indication of technique factors*—(1) *Visual indication.* The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(2) *Timers.* Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(i) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(ii) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) *Automatic exposure controls.* When an automatic exposure control is provided:

(i) Indication shall be made on the control panel when this mode of operation is selected;

(ii) When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;

(iii) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(iv) A visible signal shall indicate when an exposure has been terminated at the limits described in paragraph (a)(3)(iii) of this section, and manual resetting shall be required before further automatically timed exposures can be made.

(4) *Accuracy.* Deviation of technique factors from indicated values shall not exceed the limits given in the information provided in accordance with § 1020.30(h)(3).

(b) *Reproducibility.* The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3):

(1) *Coefficient of variation.* For any specific combination of selected technique factors, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05.

(2) *Measuring compliance.* Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978 shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

(c) *Linearity.* The following requirement applies when the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3) for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) *Average exposure ratios.* The average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is:

$X_1 - X_2 | \leqq 0.10 (X_1 + X_2)$; where X_1 and X_2 are the average mR/mAs values obtained at each of two consecutive tube current settings.

(2) *Measuring compliance.* Determination of compliance will be based on 10 exposures at each of two consecutive x-ray tube current settings made within 1 hour. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors. Where tube current selection is continuous, X_1 and X_2 shall be ob-

tained at current settings differing by no greater than a factor of 2.

(d) *Field limitation and alignment for mobile and stationary general purpose x-ray systems.* Except when spot-film devices or special attachments for mammography are in service, mobile and stationary general purpose radiographic x-ray systems shall meet the following requirements:

(1) *Variable x-ray field limitation.* There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 by 5 centimeters.

(2) *Visual definition.* (i) Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

(iii) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 millimeter.

(e) *Field limitation and alignment on stationary general purpose x-ray equipment.* Except when spot-film devices or special attachments for mammography are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in paragraph (d) of this section:

(1) *Field indication and alignment.* (i) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(ii) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(iii) Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

(iv) Compliance measurements will be made at discrete SID's and image receptor dimensions in common clinical use (such as SID's of 36, 40, 48, and 72 inches and nominal image receptor dimensions of 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

(2) *Positive beam limitation (PBL).* The requirements of this paragraph shall apply to stationary, general-purpose radiographic systems which contain a tube housing assembly, an x-ray control, and, for those systems so equipped, a table, all certified in accordance with § 1020.30(c). Means shall be provided for PBL such that x-ray production is prevented when:

(i) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or

(ii) The sum of the length and width differences as stated in paragraph (e)(2)(i) of this section without regard to sign exceeds 4 percent of the SID.

(3) *Conditions for positive beam limitation.* PBL shall be provided whenever all the following conditions are met:

(i) The image receptor is inserted into a permanently mounted cassette holder;

(ii) The image receptor length and width are each less than 50 centimeters;

(iii) The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

(iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and

(v) Neither tomographic nor stereoscopic radiography is being performed.

(4) *Measuring compliance.* Compliance with the requirements of paragraph (e)(2) of this section shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of paragraph (e)(3) of this section are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

(5) *Operator initiated undersizing.* The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 by 5 centimeters. Return to PBL function as described in paragraph (e)(2) of this section shall occur automatically upon any change of image receptor size or SID.

(6) *Override of positive beam limitation.* A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SID's and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It may not be possible to remove the key while the PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

(f) *Field limitation on radiographic x-ray equipment other than general purpose radiographic systems*—(1) *Equipment for use with intraoral image receptors.* Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and

(ii) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

(2) *X-ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(3) *Systems designed for or provided with special attachments for mammography.* Radiographic systems designed only for mammography and general purpose radiographic systems, when special attachments for mammogra-

phy are in service, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system which performs as prescribed in paragraphs (f)(4) (i), (ii), and (iii) of this section. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in paragraphs (f)(4) (ii) and (iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(4) *Other x-ray systems.* Radiographic systems not specifically covered in paragraphs (d), (e), (f)(2) and (3), and (g) of this section and systems covered in paragraph (f)(1) of this section, which also are designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID,or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(i) A system which performs in accordance with paragraphs (d) and (e)(1) of this section; or, when alignment means are also provided, may be met with either:

(ii) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(iii) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(g) *Field limitation and alignment for spot-film devices.* The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the film is greater than the selected portion of the film. If the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

(2) The total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor shall not exceed 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum without regard to sign of the misalignment along any two orthogonal dimensions shall not exceed 4 percent of the SID. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam

is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(3) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size, at the greatest SID, shall be equal to or less than 5 by 5 centimeters.

(4) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.

(5) A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

(h) *Source-skin distance.* (1) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(i) Eighteen centimeters if operable above 50 kilovolts peak, or

(ii) Ten centimeters if not operable above 50 kilovolts peak.

(2) Mobile or portable x-ray systems other than dental shall be provided with means to limit source-to-skin distance to not less than 30 centimeters.

(i) *Beam-on indicators.* The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(j) *Multiple tubes.* Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(k) *Standby radiation from capacitor energy storage equipment.* Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The response time of the (radiation measuring) instrument system shall be no less than 3 and no greater than 20 seconds.

(l) *Transmission limit for image receptor supporting devices used for mammography.* For x-ray systems manufactured after September 5, 1978 which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.1 milliroentgen for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of the tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

[38 FR 28632, Oct. 15, 1973, as amended at 39 FR 36008, Oct. 7, 1974; 42 FR 10986, Feb. 25, 1977; 42 FR 44232, Sept. 2, 1977; 42 FR 58169, Nov. 8, 1977; 44 FR 29654, May 22, 1979; 45 FR 27928, Apr. 25, 1980; 47 FR 50215, Nov. 5, 1982; 49 FR 34712, Aug. 31, 1984]

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopy and for the recording of images through an image intensifier except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Primary protective barrier*—(1) *Limitation of useful beam.* The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation form the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in § 1020.30(g). Additionally, the manufacturer shall provide to users, pursuant to § 1020.32(h)(1)(i), precautions concerning the importance of remote control operation.

(2) *Measuring compliance.* The entrance exposure rate shall be measured in accordance with paragraph (d) of this section. The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(b) *Field limitation*—(1) *Nonimage-intensified fluoroscopy.* (i) The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of the field size. The minimum field size at the greatest SID shall be equal to or less than 5-by-5 centimeters.

(ii) For equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with § 1020.32(b)(1)(i) shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(2) *Image-intensified fluoroscopy.* (i) For image-intensified fluoroscopic equipment other than radiation therapy simulation systems, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(ii) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(iii) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with § 1020.32(b)(2)(i) shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(iv) Means shall be provided to permit further limitation of the field.

Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5-by-5 centimeters or less.

(3) If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

(c) *Activation of tube.* X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(d) *Entrance exposure rate limits*—(1) *Equipment with automatic exposure rate control.* Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens per minute at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images, or

(ii) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(2) *Equipment without automatic exposure rate control.* Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images, or

(ii) When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(3) *Measuring compliance.* Compliance with this paragraph (d) shall be determined as follows:

(i) If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle.

(ii) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(iii) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(4) *Exemptions.* Fluoroscopic radiation therapy simulation systems are exempt from this requirement.

(e) *Indication of potential and current.* During fluoroscopy and cinefluorography x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated values shall not exceed the maximum deviation as stated by the manufacturer in accordance with § 1020.30(h)(3).

(f) *Source-skin distance.* Means shall be provided to limit the source-skin distance to not less than 38 centimeters on stationary fluoroscopes and to not less than 30 centimeters on mobile fluoroscopes. In addition, for image-intensified fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 centimeters. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in § 1020.30(h).

(g) *Fluoroscopic timer.* Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. As an alternative to the requirements of this paragraph, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

(h) *Mobile fluoroscopes.* In addition to the foregoing requirements of this section, mobile fluoroscopes shall provide intensified imaging.

[38 FR 28632, Oct. 15, 1973, as amended at 39 FR 35008, Oct. 7, 1974; 42 FR 10986, Feb. 25, 1977; 44 FR 29654, May 22, 1979; 45 FR 27928, Apr. 25, 1980; 47 FR 50215, Nov. 5, 1982; 49 FR 34712, Aug. 31, 1984]

§ 1020.33 Computed tomography (CT) equipment.

(a) *Applicability.* (1) The provisions of this section, except for paragraphs (b), (c)(1), and (c)(2) are applicable as specified herein to CT x-ray systems manufactured or remanufactured on or after September 3, 1985.

(2) The provisions of paragraphs (b), (c)(1), and (c)(2) are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984.

(b) *Definitions.* As used in this section, the following definitions apply:

(1) "Computed tomography dose index (CTDI)" means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan; that is:

$$\mathrm{CTDI} = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\,dz$$

Where:

z=position along a line perpendicular to the tomographic plane.

D(z)=Dose at position z.

T=Nominal tomographic section thickness.

n=Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

(2) "Contrast scale" means the change in linear attenuation coefficient per CT number relative to water; that is:

$$\text{Contrast scale} = \frac{\mu_x - \mu_w}{(CT)_x - (CT)_w}$$

Where:

μ_w = Linear attenuation coefficient of water.

μ_x = Linear attenuation coefficient of material of interest.

$(CT)_w$ = CT number of water.

$(CT)_x$ = CT number of material of interest.

(3) "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors as defined in § 1020.30(b)(36).

(4) "CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

(5) [Reserved]

(6) "CT dosimetry phantom" means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. The means used for placement of a dosimeter(s) (i.e., hole size) and the type of dosimeter(s) used is at the discretion of the manufacturer. Any effect on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(7) "Dose profile" means the dose as a function of position along a line.

(8) "Modulation transfer function" means the modulus of the Fourier transform of the impulse response of the system.

(9) "Multiple tomogram system" means a CT x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

(10) "Noise" means the standard deviation of the fluctuations in CT number expressed as a percent of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{\mu_w}$$

Where:

CS = Contrast scale.

μ_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CT numbers of picture elements in a specified area of the CT image.

(11) "Nominal tomographic section thickness" means the full-width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

(12) "Picture element" means an elemental area of a tomogram.

(13) "Remanufacturing" means modifying a CT system in such a way that the resulting dose and imaging performance become substantially equivalent to any CT x-ray system manufactured by the original manufacturer on or after November 29, 1984. Any reference in this section to "manufacture", "manufacturer", or "manufacturing" includes remanufacture, remanufacturer, or remanufacturing, respectively.

(14) "Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

(15) "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operations.

(16) "Sensitivity profile" means the relative response of the CT x-ray system as a function of position along

a line perpendicular to the tomographic plane.

(17) "Single tomogram system" means a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

(18) "Tomographic plane" means that geometric plane which the manufacturer identifies as corresponding to the output tomogram.

(19) "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

(c) *Information to be provided for users.* Each manufacturer of a CT x-ray system shall provide the following technical and safety information, in addition to that required under § 1020.30(h), to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution of such information. This information shall be identified and provided in a separate section of the user's instruction manual or in a separate manual devoted only to this information.

(1) *Conditions of operation.* A statement of the CT conditions of operation used to provide the information required by paragraph (c) (2) and (3) of this section.

(2) *Dose information.* The following dose information obtained by using the CT dosimetry phantom. For any CT x-ray system designed to image both the head and body, separate dose information shall be provided for each application. All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuating materials present.

(i) The CTDI at the following locations in the dosimetry phantom:

(*a*) Along the axis of rotation of the phantom.

(*b*) Along a line parallel to the axis of rotation and 1.0 centimeter interior to the surface of the phantom with the phantom positioned so that CTDI is the maximum obtainable at this depth.

(*c*) Along lines parallel to the axis of rotation and 1.0 centimeter interior to the surface of the phantom at positions 90, 180, and 270 degrees from the position in paragraph (c)(2)(i)(*b*) of this section. The CT conditions of operation shall be the typical values suggested by the manufacturer for CT of the head or body. The location of the position where the CTDI is maximum as specified in paragraph (c)(2)(i)(*b*) of this section shall be given by the manufacturer with respect to the housing of the scanning mechanism or other readily identifiable feature of the CT x-ray system in such a manner as to permit placement of the dosimetry phantom in this orientation.

(ii) The CTDI in the center location of the dosimetry phantom for each selectable CT condition of operation that varies either the rate or duration of x-ray exposure. This CTDI shall be presented as a value that is normalized to the CTDI in the center location of the dosimetry phantom from paragraph (c)(2)(i) of this section, with the CTDI of paragraph (c)(2)(i) of this section having a value of one. As each individual CT condition of operation is changed, all other independent CT conditions of operation shall be maintained at the typical values described in paragraph (c)(2)(i) of this section. These data shall encompass the range of each CT condition of operation stated by the manufacturer as appropriate for CT of the head or body. When more than three selections of a CT condition of operation are available, the normalized CTDI shall be provided, at least, for the minimum, maximum, and mid-range value of the CT condition of operation.

(iii) The CTDI at the location coincident with the maximum CTDI at 1 centimeter interior to the surface of the dosimetry phantom for each selectable peak tube potential. When more than three selections of peak tube potential are available, the normalized CTDI shall be provided, at least, for the minimum, maximum, and a typical value of peak tube potential. The CTDI shall be presented as a value that is normalized to the maximum CTDI located at 1 centimeter interior to the surface of the dosimetry phantom from paragraph (c)(2)(i) of this section, with the CTDI of paragraph (c)(2)(i) of this section having a value of one.

(iv) The dose profile in the center location of the dosimetry phantom for each selectable nominal tomographic section thickness. When more than three selections of nominal tomographic section thicknesses are available, the information shall be provided, at least, for the minimum, maximum, and midrange value of nominal tomographic section thickness. The dose profile shall be presented on the same graph and to the same scale as the corresponding sensitivity profile required by paragraph (c)(3)(iv) of this section.

(v) A statement of the maximum deviation from the values given in the information provided according to paragraph (c)(2) (i), (ii), (iii), and (iv) of this section. Deviation of actual values may not exceed these limits.

(3) *Imaging performance information.* The following performance data shall be provided for the CT conditions of operation used to provide the information required by paragraph (c)(2)(i) of this section. All other aspects of data collection, including the x-ray attenuation properties of the material in the tomographic section, shall be similar to those used to provide the dose information required by paragraph (c)(2)(i) of this section. For any CT x-ray system designed to image both the head and body, separate imaging performance information shall be provided for each application.

(i) A statement of the noise.

(ii) A graphical presentation of the modulation transfer function for the same image processing and display mode as that used in the statement of the noise.

(iii) A statement of the nominal tomographic section thickness(es).

(iv) A graphical presentation of the sensitivity profile, at the location corresponding to the center location of the dosimetry phantom, for each selectable nominal tomographic section thickness for which the dose profile is given according to paragraph (c)(2)(iv) of this section.

(v) A description of the phantom or device and test protocol or procedure used to determine the specifications and a statement of the maximum deviation from the specifications provided in accordance with paragraphs (c)(3) (i), (ii), (iii), and (iv) of this section. Deviation of actual values may not exceed these limits.

(d) *Quality assurance.* The manufacturer of any CT x-ray system shall provide the following with each system. All information required by this subsection shall be provided in a separate section of the user's instructional manual.

(1) A phantom(s) capable of providing an indication of contrast scale, noise, nominal tomographic section thickness, the spatial resolution capability of the system for low and high contrast objects, and measuring the mean CT number of water or a reference material.

(2) Instructions on the use of the phantom(s) including a schedule of testing appropriate for the system, allowable variations for the indicated parameters, and a method to store as records, quality assurance data.

(3) Representative images obtained with the phantom(s) using the same processing mode and CT conditions of operation as in paragraph (c)(3) of this section for a properly functioning system of the same model. The representative images shall be of two forms as follows:

(i) Photographic copies of the images obtained from the image display device.

(ii) Images stored in digital form on a storage medium compatible with the CT x-ray system. The CT x-ray system shall be provided with the means to display these images on the image display device.

(e) [Reserved]

(f) *Control and indication of conditions of operation*—(1) *Visual indication.* The CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of the CT conditions of operation shall be visible from any position from which scan initiation is possible.

(2) *Timers.* (i) Means shall be provided to terminate the x-ray exposure automatically by either deenergizing the x-ray source or shuttering the x-ray beam in the event of equipment

failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function. A visible signal shall indicate when the x-ray exposure has been terminated through these means and manual resetting of the CT conditions of operation shall be required prior to the initiation of another scan.

(ii) Means shall be provided such that the exposure from the system does not exceed the radiation levels specified in § 1020.30(k) except when x-ray transmission data are being collected for use in image production or technique factor selection.

(iii) Means shall be provided so that the operator can terminate the x-ray exposure at any time during a scan, or series of scans under x-ray system control, of greater than one-half second duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

(g) *Tomographic plane indication and alignment.* (1) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(2) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The relationship of the reference plane to the planes of the tomograms shall be provided to the user in addition to other information provided according to § 1020.30(h). This reference plane can be offset from the location of the tomographic planes.

(3) The distance between the indicated location of the tomographic plane or reference plane and its actual location may not exceed 5 millimeters.

(4) For any offset alignment system, the manufacturer shall provide specific instructions with respect to the use of this system for patient positioning, in addition to other information provided according to § 1020.30(h).

(5) If a mechanism using a light source is used to satisfy the requirements of paragraphs (g) (1) and (2) of this section, the light source shall allow visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(h) *Beam-on and shutter status indicators.* (1) Means shall be provided on the control and on or near the housing of the scanning mechanism to provide visual indication when and only when x rays are produced and, if applicable, whether the shutter is open or closed. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for one-half second. Indicators at or near the housing of the scanning mechanism shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

(2) For systems that allow high voltage to be applied to the x-ray tube continuously and that control the emission of x rays with a shutter, the radiation emitted may not exceed 100 milliroentgens (2.58×10^{-5} coulomb/kilogram) in 1 hour at any point 5 centimeters outside the external surface of the housing of the scanning mechanism when the shutter is closed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimensions greater than 20 centimeters.

(i) *Scan increment accuracy.* The deviation of indicated scan increment from actual scan increment may not exceed 1 millimeter. Compliance shall be measured as follows: The determination of the deviation of indicated versus actual scan increment shall be based on measurements taken with a mass 100 kilograms or less, on the patient support device. The patient support device shall be incremented from a typical starting position to the maximum incrementation distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(j) *CT number mean and standard deviation.* (1) A method shall be provided to calculate the mean and standard deviation of CT numbers for an array of picture elements about any location in the image. The number of elements in this array shall be under user control.

(2) The manufacturer shall provide specific instructions concerning the use of the method provided for calculation of CT number mean and standard deviation in addition to other information provided according to § 1020.30(h).

(The information collection requirements in paragraphs (c), (d), (g), and (j) were approved by the Office of Management and Budget under control number 0910-0025)

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f); secs. 201, 501, 502, 701, 52 Stat. 1040-1042 as amended, 1049-1051 as amended, 1055-1056 as amended (21 U.S.C. 321, 351, 352, 371))

[49 FR 34712, Aug. 31, 1984; 49 37381, Sept. 24, 1984, as amended at 49 FR 47388, Dec. 4, 1984]

§ 1020.40 Cabinet x-ray systems.

(a) *Applicability.* The provisions of this section are applicable to cabinet x-ray systems manufactured or assembled on or after April 10, 1975, except that the provisions as applied to x-ray systems designed primarily for the inspection of carry-on baggage are applicable to such systems manufactured or assembled on or after April 25, 1974. The provisions of this section are not applicable to systems which are designed exclusively for microscopic examination of material, e.g., x-ray diffraction, spectroscopic, and electron microscope equipment or to systems for intentional exposure of humans to x-rays.

(b) *Definitions.* As used in this section the following definitions apply:

(1) "Access panel" means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open, and permits access to the interior of the cabinet.

(2) "Aperture" means any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x radiation.

(3) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed "cabinet") which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

(4) "Door" means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet. For the purposes of paragraph (c)(4)(i) of this section, inflexible hardware rigidly affixed to the door shall be considered part of the door.

(5) "Exposure" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.

(6) "External surface" means the outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.

(7) "Floor" means the underside external surface of the cabinet.

(8) "Ground fault" means an accidental electrical grounding of an electrical conductor.

(9) "Port" means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.

(10) "Primary beam" means the x radiation emitted directly from the from

the target and passing through the window of the x-ray tube.

(11) "Safety interlock" means a device which is intended to prevent the generation of x radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.

(12) "X-ray system" means an assemblage of components for the controlled generation of x-rays.

(13) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) *Requirements*—(1) *Emission limit.* (i) Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface.

(ii) Compliance with the exposure limit in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over a cross-sectional area of ten square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface, and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x radiation.

(2) *Floors.* A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.

(3) *Ports and apertures.* (i) The insertion of any part of the human body through any port into the primary beam shall not be possible.

(ii) The insertion of any part of the human body through any aperture shall not be possible.

(4) *Safety interlocks.* (i) Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.

(ii) Each access panel shall have at least one safety interlock.

(iii) Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with paragraph (c)(6)(ii) of this section shall be necessary for resumption of x-ray generation.

(iv) Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.

(5) *Ground fault.* A ground fault shall not result in the generation of x-rays.

(6) *Controls and indicators for all cabinet x-ray systems.* For all systems to which this section is applicable there shall be provided:

(i) A key-actuated control to insure that x-ray generation is not possible with the key removed.

(ii) A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.

(iii) Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled "X-RAY ON".

(iv) Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel, and port, and is legibly labeled "X-RAY ON".

(7) *Additional controls and indicators for cabinet x-ray systems designed to admit humans.* For cabinet x-ray systems designed to admit humans there shall also be provided:

(i) A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

(ii) No means by which x-ray generation can be initiated from within the cabinet.

(iii) Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause failure of both the audible and visible warning signals.

(iv) A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second.

(v) Signs indicating the meaning of the warning signals provided pursuant to paragraphs (c)(7)(iii) and (iv) of this section and containing instructions for the use of the control provided pursuant to paragraph (c)(7)(i) of this section. These signs shall be legible, accessible to view, and illuminated when the main power control is in the "on" position.

(8) *Warning labels.* (i) There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:

CAUTION: X-RAYS PRODUCED WHEN ENERGIZED

(ii) There shall be permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement:

CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED—X-RAY HAZARD

(9) *Instructions.* (i) Manufacturers of cabinet x-ray systems shall provide for purchasers, and to others upon request at a cost not to exceed the cost of preparation and distribution, manuals and instructions which shall include at least the following technical and safety information: Potential, current, and duty cycle ratings of the x-ray generation equipment; adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the system; and a schedule of maintenance necessary to keep the system in compliance with this section.

(ii) Manufacturers of cabinet x-ray systems which are intended to be assembled or installed by the purchaser shall provide instructions for assembly, installation, adjustment and testing of the cabinet x-ray system adequate to assure that the system is in compliance with applicable provisions of this section when assembled, installed, adjusted and tested as directed.

(10) *Additional requirements for x-ray baggage inspection systems.* X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, shall be provided with means, pursuant to paragraphs (c) (10) (i) and (ii) of this section, to insure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-radiation.

(i) During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

(ii) During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

(d) *Modification of a certified system.* The modification of a cabinet x-ray system, previously certified pursuant to § 1010.2 by any person engaged in the business of manufacturing, assembling or modifying cabinet x-ray systems shall be construed as manufacturing under the act if the modification affects any aspect of the system's performance for which this section has an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the system in accordance with the provisions of §§ 1010.2 and 1010.3 of this chapter.

[39 FR 12986, Apr. 10, 1974]

PART 1030—PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

§ 1030.10 Microwave ovens.

(a) *Applicability.* The provisions of this standard are applicable to microwave ovens manufactured after October 6, 1971.

(b) *Definitions.* (1) "Microwave oven" means a device designed to heat, cook, or dry food through the application of electromagnetic energy at frequencies assigned by the Federal Communications Commission in the normal ISM heating bands ranging from 890 megahertz to 6,000 megahertz. As defined in this standard, "microwave ovens" are limited to those manufactured for use in homes, restaurants, food vending, or service establishments, on interstate carriers, and in similar facilities.

(2) "Cavity" means that portion of the microwave oven in which food may be heated, cooked, or dried.

(3) "Door" means the movable barrier which prevents access to the cavity during operation and whose function is to prevent emission of microwave energy from the passage or opening which provides access to the cavity.

(4) "Safety interlock" means a device or system of devices which is intended to prevent generation of microwave energy when access to the cavity is possible.

(5) "Service adjustments or service procedures" means those servicing methods prescribed by the manufacturer for a specific product model.

(6) "Stirrer" means that feature of a microwave oven which is intended to provide uniform heating of the load by constantly changing the standing wave pattern within the cavity or moving the load.

(7) "External surface" means the outside surface of the cabinet or enclosure provided by the manufacturer as part of the microwave oven, including doors, door handles, latches, and control knobs.

(8) "Equivalent plane-wave power density" means the square of the root-mean-square (rms) electric field strength divided by the impedance of free space (377 ohms).

(c) *Requirements*—(1) *Power density limit.* The equivalent plane-wave power density existing in the proximity of the external oven surface shall not exceed 1 milliwatt per square centimeter at any point 5 centimeters or more from the external surface of the oven, measured prior to acquisition by a purchaser, and, thereafter, 5 milliwatts per square centimeter at any such point.

(2) *Safety interlocks.* (i) Microwave ovens shall have a minimum of two operative safety interlocks. At least one operative safety interlock on a fully assembled microwave oven shall not be operable by any part of the human body, or any object with a straight insertable length of 10 centimeters. Such interlock must also be concealed, unless its actuation is prevented when access to the interlock is possible. Any visible actuator or device to prevent actuation of this safety interlock must not be removable without disassembly of the oven or its door. A magnetically operated interlock is considered to be concealed, or its actuation is considered to be prevented, only if a test magnet held in place on the oven by gravity or its own attraction cannot operate the safety interlock. The test magnet shall be capable of lifting vertically at zero air gap at least 4.5 kilograms, and at 1 centimeter air gap at least 450 grams when the face of the magnet, which is toward the interlock when the magnet is in the test position, is pulling against one of the large faces of a mild steel armature having

dimensions of 80 millimeters by 50 millimeters by 8 millimeters.

(ii) Failure of any single mechanical or electrical component of the microwave oven shall not cause all safety interlocks to be inoperative.

(iii) Service adjustments or service procedures on the microwave oven shall not cause the safety interlocks to become inoperative or the microwave radiation emission to exceed the power density limits of this section as a result of such service adjustments or procedures.

(iv) Microwave radiation emission in excess of the limits specified in paragraph (c)(1) of this section shall not be caused by insertion of an insulated wire through any opening in the external surfaces of a fully assembled oven into the cavity, waveguide, or other microwave-energy-containing spaces while the door is closed, provided the wire, when inserted, could consist of two straight segments forming an obtuse angle of not less than 170 degrees.

(v) One (the primary) required safety interlock shall prevent microwave radiation emission in excess of the requirement of paragraph (c)(1) of this section; the other (secondary) required safety interlock shall prevent microwave radiation emission in excess of 5 milliwatts per square centimeter at any point 5 centimeters or more from the external surface of the oven. The two required safety interlocks shall be designated as primary or secondary in the service instructions for the oven.

(vi) A means of monitoring one or both of the required safety interlocks shall be provided which shall cause the oven to become inoperable and remain so until repaired if the required safety interlock(s) should fail to perform required functions as specified in this section. Interlock failures shall not disrupt the monitoring function.

(3) *Measurement and test conditions.* (i) Compliance with the power density limit in paragraph (c)(1) of this section shall be determined by measurement of the equivalent plane-wave power density made with an instrument which reaches 90 percent of its steady-state reading within 3 seconds, when the system is subjected to a step-function input signal. Tests for compliance shall account for all measurement errors and uncertainties to ensure that the equivalent plane-wave power density does not exceed the limit prescribed by paragraph (c)(1) of this section.

(ii) Microwave ovens shall be in compliance with the power density limits if the maximum reading obtained at the location of greatest microwave radiation emission, taking into account all measurement errors and uncertainties, does not exceed the limit specified in paragraph (c)(1) of this section, when the emission is measured through at least one stirrer cycle. As provided in § 1010.13 of this chapter, a manufacturer may request alternative test procedures if, as a result of the stirrer characteristics of a microwave oven, such oven is not susceptible to testing by the procedures described in this paragraph.

(iii) Measurements shall be made with the microwave oven operating at its maximum output and containing a load of 275±15 milliliters of tap water initially at 20°±5° centigrade placed within the cavity at the center of the load-carrying surface provided by the manufacturer. The water container shall be a low form 600-milliliter beaker having an inside diameter of approximately 8.5 centimeters and made of an electrically nonconductive material such as glass or plastic.

(iv) Measurements shall be made with the door fully closed as well as with the door fixed in any other position which allows the oven to operate.

(4) *User instructions.* Manufacturers of microwave ovens to which this section is applicable shall provide, or cause to be provided, with each oven, radiation safety instructions which:

(i) Occupy a separate section and are an integral part of the regularly supplied users' manual and cookbook, if supplied separately, and are located so as to elicit the attention of the reader.

(ii) Are as legible and durable as other instructions with the title emphasized to elicit the attention of the reader by such means as bold-faced type, contrasting color, a heavy-lined border, or by similar means.

(iii) Contain the following wording:

PRECAUTIONS TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY

(*a*) Do not attempt to operate this oven with the door open since open-door operation can result in harmful exposure to microwave energy. It is important not to defeat or tamper with the safety interlocks.

(*b*) Do not place any object between the oven front face and the door or allow soil or cleaner residue to accumulate on sealing surfaces.

(*c*) Do not operate the oven if it is damaged. It is particularly important that the oven door close properly and that there is no damage to the: (*1*) Door (bent), (*2*) hinges and latches (broken or loosened), (*3*) door seals and sealing surfaces.

(*d*) The oven should not be adjusted or repaired by anyone except properly qualified service personnel.

(iv) Include additional radiation safety precautions or instructions which may be necessary for particular oven designs or models, as determined by the Director, Bureau of Radiological Health or the manufacturer.

(5) *Service instructions.* Manufacturers of microwave ovens to which this section is applicable shall provide or cause to be provided to servicing dealers and distributors and to others upon request, for each oven model, adequate instructions for service adjustments and service procedures, and, in addition, radiation safety instructions which:

(i) Occupy a separate section and are an integral part of the regularly supplied service manual and are located so as to elicit the attention of the reader.

(ii) Are as legible and durable as other instructions with the title emphasized so as to elicit the attention of the reader by such means as boldfaced type, contrasting color, a heavy-lined border, or by similar means.

(iii) Contain the following wording:

PRECAUTIONS TO BE OBSERVED BEFORE AND DURING SERVICING TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY

(*a*) Do not operate or allow the oven to be operated with the door open.

(*b*) Make the following safety checks on all ovens to be serviced before activating the magnetron or other microwave source, and make repairs as necessary: (*1*) Interlock operation, (*2*) proper door closing, (*3*) seal and sealing surfaces (arcing, wear, and other damage), (*4*) damage to or loosening of hinges and latches, (*5*) evidence of dropping or abuse.

(*c*) Before turning on microwave power for any service test or inspection within the microwave generating compartments, check the magnetron, wave guide or transmission line, and cavity for proper alignment, integrity, and connections.

(*d*) Any defective or misadjusted components in the interlock, monitor, door seal, and microwave generation and transmission systems shall be repaired, replaced, or adjusted by procedures described in this manual before the oven is released to the owner.

(*e*) A Microwave leakage check to verify compliance with the Federal performance standard should be performed on each oven prior to release to the owner.

(iv) Include additional radiation safety precautions or instructions which may be necessary for particular oven designs or models, as determined by the Director, Bureau of Radiological Health or the manufacturer.

(6) *Warning labels.* Except as provided in paragraph (c)(6)(iv) of this section, microwave ovens shall have the following warning labels:

(i) A label, permanently attached to or inscribed on the oven, which shall be legible and readily viewable during normal oven use, and which shall have the title emphasized and be so located as to elicit the attention of the user. The label shall bear the following warning statement:

PRECAUTIONS FOR SAFE USE TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY

DO NOT Attempt to Operate This Oven With:

(*a*) Object Caught in Door.

(*b*) Door That Does Not Close Properly.

(*c*) Damaged Door, Hinge, Latch, or Sealing Surface.

(ii) A label, permanently attached to or inscribed on the external surface of the oven, which shall be legible and readily viewable during servicing, and which shall have the word "CAUTION" emphasized and be so located as to elicit the attention of service personnel. The label shall bear the following warning statement:

CAUTION: This Device is to be Serviced Only by Properly Qualified Service Personnel. Consult the Service Manual for Proper Service Procedures to Assure Continued Compliance with the Federal Performance

Standard for Microwave Ovens and for Precautions to be Taken to Avoid Possible Exposure to Excessive Microwave Energy.

(iii) The labels provided in accordance with paragraphs (c)(6)(i) and (ii) of this section shall bear only the statements specified in that paragraph, except for additional radiation safety warnings or instructions which may be necessary for particular oven designs or models, as determined by the Director, Bureau of Radiological Health or the manufacturer.

(iv) Upon application by a manufacturer, the Director, Bureau of Radiological Health, Food and Drug Administration, may grant an exemption from one or more of the statements (radiation safety warnings) specified in paragraph (c)(6)(i) of this section. Such exemption shall be based upon a determination by the Director that the microwave oven model for which the exemption is sought should continue to comply with paragraphs (c) (1), (2), and (3) of this section under the adverse condition of use addressed by such precautionary statement(s). An original and two copies of applications shall be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of the written portion of the application, including supporting data and information, and the Director's action on the application will be maintained by the Branch for public review. The application shall include:

(*a*) The specific microwave oven model(s) for which the exemption is sought.

(*b*) The specific radiation safety warning(s) from which exemption is sought.

(*c*) Data and information which clearly establish that one or more of the radiation safety warnings in paragraph (c)(6)(i) of this section is not necessary for the specified microwave oven model(s).

(*d*) Such other information and a sample of the applicable product if required by regulation or by the Director, Bureau of Radiological Health, to evaluate and act on the application.

(Sec. 358, 82 Stat. 1177-1179; 42 U.S.C. 263f; sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[38 FR 28640, Oct. 15, 1973, as amended at 40 FR 14752, Apr. 4, 1975; 40 FR 52007, Nov. 7, 1975; 46 FR 8461, Jan. 27, 1981; 48 FR 57482, Dec. 30, 1983; 50 FR 13566, Apr. 5, 1985]

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

Sec.
1040.10 Laser products.
1040.11 Specific purpose laser products.
1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.
1040.30 High-intensity mercury vapor discharge lamps.

AUTHORITY: Secs. 358, 360A, 82 Stat. 1177-1179, 1182 (42 U.S.C. 263f, 263i); 21 CFR 5.10.

§ 1040.10 Laser products.

(a) *Applicability.* The provisions of this section and § 1040.11, as amended, are applicable as specified to all laser products manufactured or assembled after August 1, 1976, except when:

(1) Such a laser product is either sold to a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, or

(2) Sold by or for a manufacturer of an electronic product for use as a component (or replacement) in such electronic product, provided that such laser product:

(i) Is accompanied by a general warning notice that adequate instructions for the safe installation of the laser product are provided in servicing information available from the complete laser product manufacturer under paragraph (h)(2)(ii) of this section, and should be followed,

(ii) Is labeled with a statement that it is designated for use solely as a component of such electronic product and therefore does not comply with the appropriate requirements of this section and § 1040.11 for complete laser products, and

(iii) Is not a removable laser system as described in paragraph (c)(2) of this section; and

(3) The manufacturer of such a laser product, if manufactured after August 20, 1986:

(i) Registers, and provides a listing by type of such laser products manufactured that includes the product name, model number and laser medium or emitted wavelength(s). The registration and listing shall include the name and address of the manufacturer and shall be submitted to the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, MD 20857.

(ii) Maintains and allows access to any sales, shipping, or distribution records that identify the purchaser of such a laser product by name and address, the product by type, the number of units sold, and the date of sale (shipment). These records shall be maintained and made available as specified in § 1002.31.

(b) *Definitions.* As used in this section and § 1040.11, the following definitions apply:

(1) "Accessible emission level" means the magnitude of accessible laser or collateral radiation of a specific wavelength and emission duration at a particular point as measured according to paragraph (e) of this section. Accessible laser or collateral radiation is radiation to which human access is possible, as defined in paragraphs (b) (12), (15), and (22) of this section.

(2) "Accessible emission limit" means the maximum accessible emission level permitted within a particular class as set forth in paragraphs (c), (d), and (e) of this section.

(3) "Aperture" means any opening in the protective housing or other enclosure of a laser product through which laser or collateral radiation is emitted, thereby allowing human access to such radiation.

(4) "Aperture stop" means an opening serving to limit the size and to define the shape of the area over which radiation is measured.

(5) "Class I laser product" means any laser product that does not permit access during the operation to levels of laser radiation in excess of the accessible emission limits contained in Table I of paragraph (d) of this section.[1]

(6) "Class IIa laser product" means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table I, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table II-A of paragraph (d) of this section.[2]

(7) "Class II laser product" means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table II-A, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table II of paragraph (d) of this section.[3]

(8) "Class IIIa laser product" means any laser product that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in Table II, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table III-A of paragraph (d) of this section.[4]

(9) "Class IIIb laser product" means any laser product that permits human access during operation to levels of laser radiation in excess of the accessible emission limits of Table III-A, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table III-B of paragraph (d) of this section.[5]

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[1] Class I levels of laser radiation are not considered to be hazardous.

[2] Class IIa levels of laser radiation are not considered to be hazardous if viewed for any period of time less than or equal to 1 × 10^3 seconds but are considered to be a chronic viewing hazard for any period of time greater than 1 × 10^3 seconds.

[3] Class II levels of laser radiation are considered to be a chronic viewing hazard.

[4] Class IIIa levels of laser radiation are considered to be, depending upon the irradiance, either an acute intrabeam viewing hazard or chronic viewing hazard, and an acute viewing hazard if viewed directly with optical instruments.

[5] Class IIIb levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct radiation.

(10) "Class III laser product" means any Class IIIa or Class IIIb laser product.

(11) "Class IV laser product" means any laser that permits human access during operation to levels of laser radiation in excess of the accessible emission limits contained in Table III-B of paragraph (d) of this section.[6]

(12) "Collateral radiation" means any electronic product radiation, except laser radiation, emitted by a laser product as a result of the operation of the laser(s) or any component of the laser product that is physically necessary for the operation of the laser(s).

(13) "Demonstration laser product" means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display, or artistic composition. The term "demonstration laser product" does not apply to laser products which are not manufactured, designed, intended, or promoted for such purposes, even though they may be used for those purposes or are intended to demonstrate other applications.

(14) "Emission duration" means the temporal duration of a pulse, a series of pulses, or continuous operation, expressed in seconds, during which human access to laser or collateral radiation could be permitted as a result of operation, maintenance, or service of a laser product.

(15) "Human access" means the capacity to intercept laser or collateral radiation by any part of the human body. For laser products that contain Class IIIb or IV levels of laser radiation, "human access" also means access to laser radiation that can be reflected directly by any single introduced flat surface from the interior of the product through any opening in the protective housing of the product.

(16) "Integrated radiance" means radiant energy per unit area of a radiating surface per unit solid angle of emission, expressed in joules per square centimeter per steradian ($\mathrm{Jcm^{-2}\,sr^{-1}}$).

(17) "Invisible radiation" means laser or collateral radiation having wavelengths of equal to or greater than 180 nm but less than or equal to 400 nm or greater than 710 nm but less than or equal to 1.0×10^6 nm (1 millimeter).

(18) "Irradiance" means the time-averaged radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimeter ($\mathrm{W\,cm^{-2}}$).

(19) "Laser" means any device that can be made to produce or amplify electromagnetic radiation at wavelenghts greater than 250 nm but less than or equal to 13,000 nm or, after August 20, 1986, at wavelengths equal to or greater than 180 nm but less than or equal to 1.0×10^6 nm primarily by the process of controlled stimulated emission.

(20) "Laser energy source" means any device intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries shall not be considered to constitute laser energy sources.

(21) "Laser product" means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system that is intended for use as a component of an electronic product shall itself be considered a laser product.

(22) "Laser radiation" means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph (b)(19) of this section that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop and within the appropriate solid angle of acceptance, as specified in paragraph (e) of this section.

(23) "Laser system" means a laser in combination with an appropriate laser energy source with or without additional incorporated components. See paragraph (c)(2) of this section for an

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[6] Class IV levels of laser radiation are considered to be an acute hazard to the skin and eyes from direct and scattered radiation.

explanation of the term "removable laser system."

(24) "Maintenance" means performance of those adjustments or procedures specified in user information provided by the manufacturer with the laser product which are to be performed by the user for the purpose of assuring the intended performance of the product. It does not include operation or service as defined in paragraph (b) (27) and (38) of this section.

(25) "Maximum output" means the maximum radiant power and, where applicable, the maximum radiant energy per pulse of accessible laser radiation emitted by a laser product during operation, as determined under paragraph (e) of this section.

(26) "Medical laser product" means any laser product which is a medical device as defined in 21 U.S.C. 321(h) and is manufactured, designed, intended or promoted for in vivo laser irradiation of any part of the human body for the purpose of: (i) Diagnosis, surgery, or therapy; or (ii) relative positioning of the human body.

(27) "Operation" means the performance of the laser product over the full range of its functions. It does not include maintenance or service as defined in paragraphs (b) (24) and (38) of this section.

(28) "Protective housing" means those portions of a laser product which are designed to prevent human access to laser or collateral radiation in excess of the prescribed accessible emission limits under conditions specified in this section and in § 1040.11.

(29) "Pulse duration" means the time increment measured between the half-peak-power points at the leading and trailing edges of a pulse.

(30) "Radiance" means time-averaged radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian ($\mathrm{W\ cm^{-2} sr^{-1}}$).

(31) "Radiant energy" means energy emitted, transferred or received in the form of radiation, expressed in joules (J).

(32) "Radiant exposure" means the radiant energy incident on an element of a surface divided by the area of the element, expressed in joules per square centimeter ($\mathrm{Jcm^{-2}}$)

(33) "Radiant power" means time-averaged power emitted, transferred or received in the form of radiation, expressed in watts (W).

(34) "Remote interlock connector" means an electrical connector which permits the connection of external remote interlocks.

(35) "Safety interlock" means a device associated with the protective housing of a laser product to prevent human access to excessive radiation in accordance with paragraph (f)(2) of this section.

(36) "Sampling interval" means the time interval during which the level of accessible laser or collateral radiation is sampled by a measurement process. The magnitude of the sampling interval in units of seconds is represented by the symbol (t).

(37) "Scanned laser radiation" means laser radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference.

(38) "Service" means the performance of those procedures or adjustments described in the manufacturer's service instructions which may affect any aspect of the product's performance for which this section and § 1040.11 have applicable requirements. It does not include maintenance or operation as defined in paragraphs (b) (24) and (27) of this section.

(39) "Surveying, leveling, or alignment laser product" means a laser product manufactured, designed, intended or promoted for one or more of the following uses:

(i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement.

(ii) Positioning or adjusting parts in proper relation to one another.

(iii) Defining a plane, level, elevation, or straight line.

(40) "Visible radiation" means laser or collateral radiation having wavelengths of greater than 400 nm but less than or equal to 710 nm.

(41) "Warning logotype" means a logotype as illustrated in either Figure 1 or Figure 2 of paragraph (g) of this section.

(42) "Wavelength" means the propagation wavelength in air of electromagnetic radiation.

(c) *Classification of laser products*—(1) *All laser products.* Each laser product shall be classified in Class I, IIa, II, IIIa, IIIb, or IV in accordance with definitions set forth in paragraphs (b)(5) through (11) of this section. The product classification shall be based on the highest accessible emission level(s) of laser radiation to which human access is possible during operation in accordance with paragraphs (d), (e), and (f)(1) of this section.

(2) *Removable laser systems.* Any laser system that is incorporated into a laser product subject to the requirements of this section and that is capable, without modification, of producing laser radiation when removed from such laser product, shall itself be considered a laser product and shall be separately subject to the applicable requirements in this subchapter for laser products of its class. It shall be classified on the basis of accessible emission of laser radiation when so removed.

(d) *Accessible emission limits.* Accessible emission limits for laser radiation in each class are specified in Tables I, II-A, II, III-A, and III-B of this paragraph. The factors, k_1 and k_2 vary with wavelength and emission duration. These factors are given in Table IV of this paragraph, with selected numerical values in Table V of this paragraph. Accessible emission limits for collateral radiation are specified in Table VI of this paragraph.

NOTES APPLICABLE TO TABLES I, II-A, II, III-A AND III-B:

(1) The factors k_1 and k_2 are wavelength-dependent correction factors determined from Table IV.

(2) The variable t in the expressions of emission limits is the magnitude of the sampling interval in units of seconds.

TABLE I

CLASS I ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration (seconds)	Class I-Accessible emission limits		
		(value)	(unit)	(quantity)**
≥ 180 but ≤ 400	$\leq 3.0 \times 10^4$	$2.4 \times 10^{-5} k_1 k_2$*	Joules(J)*	radiant energy
	$>3.0 \times 10^4$	$8.0 \times 10^{-10} k_1 k_2$*	Watts(W)*	radiant power
>400 but ≤ 1400	$>1.0 \times 10^{-9}$ to 2.0×10^{-5}	$2.0 \times 10^{-7} k_1 k_2$	J	radiant energy
	$>2.0 \times 10^{-5}$ to 1.0×10^{1}	$7.0 \times 10^{-4} k_1 k_2 t^{3/4}$	J	radiant energy
	$>1.0 \times 10^{1}$ to 1.0×10^{4}	$3.9 \times 10^{-3} k_1 k_2$	J	radiant energy
	$>1.0 \times 10^{4}$	$3.9 \times 10^{-7} k_1 k_2$	W	radiant power
	and also (See paragraph (d)(4) of this section)			
	$>1.0 \times 10^{-9}$ to 1.0×10^{1}	$10 k_1 k_2 t^{1/3}$	$Jcm^{-2}sr^{-1}$	integrated radiance
	$>1.0 \times 10^{1}$ to 1.0×10^{4}	$20 k_1 k_2$	$Jcm^{-2}sr^{-1}$	integrated radiance
	$>1.0 \times 10^{4}$	$2.0 \times 10^{-3} k_1 k_2$	$Wcm^{-2}sr^{-1}$	radiance
>1400 but ≤ 2500	$>1.0 \times 10^{-9}$ to 1.0×10^{-7}	$7.9 \times 10^{-5} k_1 k_2$	J	radiant energy
	$>1.0 \times 10^{-7}$ to 1.0×10^{1}	$4.4 \times 10^{-3} k_1 k_2 t^{1/4}$	J	radiant energy
	$>1.0 \times 10^{1}$	$7.9 \times 10^{-4} k_1 k_2$	W	radiant power
>2500 but $\leq 1.0 \times 10^6$	$>1.0 \times 10^{-9}$ to 1.0×10^{-7}	$1.0 \times 10^{-2} k_1 k_2$	Jcm^{-2}	radiant exposure
	$>1.0 \times 10^{-7}$ to 1.0×10^{1}	$5.6 \times 10^{-1} k_1 k_2 t^{1/4}$	Jcm^{-2}	radiant exposure
	$>1.0 \times 10^{1}$	$1.0 \times 10^{-1} k_1 k_2 t$	Jcm^{-2}	radiant exposure

*Class I accessible emission limits for wavelengths equal to or greater than 180 nm but less than or equal to 400 nm shall not exceed the Class I accessible emission limits for the wavelengths greater than 1400 nm but less than or equal to 1.0×10^6 nm with a k_1 and k_2 of 1.0 for comparable sampling intervals.

**Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE II-A

CLASS IIa ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

CLASS IIa ACCESSIBLE EMISSION LIMITS ARE IDENTICAL TO CLASS I ACCESSIBLE EMISSION LIMITS EXCEPT WITHIN THE FOLLOWING RANGE OF WAVELENGTHS AND EMISSION DURATIONS:

Wavelength (nanometers)	Emission duration (seconds)	Class IIa-Accessible emission limits		
		(value)	(unit)	(quantity)*
>400 but ≤710	$>1.0 \times 10^{3}$	3.9×10^{-6}	W	radiant power

*Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE II

CLASS II ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

CLASS II ACCESSIBLE EMISSION LIMITS ARE IDENTICAL TO CLASS I ACCESSIBLE EMISSION LIMITS EXCEPT WITHIN THE FOLLOWING RANGE OF WAVELENGTHS AND EMISSION DURATIONS:

Wavelength (nanometers)	Emission duration (seconds)	Class II-Accessible emission limits		
		(value)	(unit)	(quantity)*
>400 but ≤710	$>2.5 \times 10^{-1}$	1.0×10^{-3}	W	radiant power

*Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE III-A

CLASS IIIa ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

CLASS IIIa ACCESSIBLE EMISSION LIMITS ARE IDENTICAL TO CLASS I ACCESSIBLE EMISSION LIMITS EXCEPT WITHIN THE FOLLOWING RANGE OF WAVELENGTHS AND EMISSION DURATIONS:				
Wavelength	Emission duration	Class IIIa-Accessible emission limits		
(nanometers)	(seconds)	(value)	(unit)	(quantity)*
>400 but ≤710	>3.8 X 10^{-4}	5.0 X 10^{-3}	W	radiant power

*Measurement parameters and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE III-B

CLASS IIIb ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength	Emission duration	Class IIIb-Accessible emission limits		
(nanometers)	(seconds)	(value)	(unit)	(quantity)*
≥180 but	≤2.5 X 10^{-1}	3.8 X $10^{-4}k_1k_2$	J	radiant energy
≤400	>2.5 X 10^{-1}	1.5 X $10^{-3}k_1k_2$	W	radiant power
>400	>1.0 X 10^{-9} to 2.5 X 10^{-1}	$10k_1k_2t^{1/3}$	Jcm^{-2}	radiant exposure
but		to a maximum value		
		of 10	Jcm^{-2}	radiant exposure
≤1400	>2.5 X 10^{-1}	5.0 X 10^{-1}	W	radiant power
>1400 but	>1.0 X 10^{-9} to 1.0 X 10^{1}	10	Jcm^{-2}	radiant exposure
≤1.0 X 10^{6}	>1.0 X 10^{1}	5.0 X 10^{-1}	W	radiant power

*Measurement parameter and test conditions shall be in accordance with paragraphs (d)(1), (2), (3), and (4), and (e) of this section.

TABLE IV

VALUES OF WAVELENGTH DEPENDENT CORRECTION FACTORS k_1 AND k_2

Wavelength (nanometers)	k_1	k_2		
180 to 302.4	1.0	1.0		
> 302.4 to 315	$10^{\left[\frac{\lambda - 302.4}{5}\right]}$	1.0		
> 315 to 400	330.0	1.0		
> 400 to 700	1.0	1.0		
> 700 to 800	$10^{\left[\frac{\lambda - 700}{515}\right]}$	if: $t \leq \frac{10100}{\lambda - 699}$ then: $k_2 = 1.0$	if: $\frac{10100}{\lambda - 699} < t \leq 10^4$ then: $k_2 = \frac{t(\lambda - 699)}{10100}$	if: $t > 10^4$ then: $k_2 = \frac{\lambda - 699}{1.01}$
> 800 to 1060	$10^{\left[\frac{\lambda - 700}{515}\right]}$	if: $t \leq 100$ then: $k_2 = 1.0$	if: $100 < t \leq 10^4$ then: $k_2 = \frac{t}{100}$	if: $t > 10^4$ then: $k_2 = 100$
> 1060 to 1400	5.0			
> 1400 to 1535	1.0	1.0		
> 1535 to 1545	$t \leq 10^{-7}$ $k_1 = 100.0$	1.0		
	$t > 10^{-7}$ $k_1 = 1.0$			
> 1545 to 1.0×10^6	1.0	1.0		

Note: The variables in the expressions are the magnitudes of the sampling interval(t), in units of seconds, and the wavelength (λ), in units of nanometers.

TABLE V

SELECTED NUMERICAL SOLUTIONS FOR k_1 AND k_2

Wavelength (nanometers)	k_1	k_2				
		$t \leq 100$	$t=300$	$t=1000$	$t=3000$	$t \geq 10{,}000$
180	1.0	1.0				
300	1.0					
302	1.0					
303	1.32					
304	2.09					
305	3.31					
306	5.25					
307	8.32					
308	13.2					
309	20.9					
310	33.1					
311	52.5					
312	83.2					
313	132.0					
314	209.0					
315	330.0					
400	330.0					
401	1.0					
500	1.0					
600	1.0					
700	1.0					
710	1.05	1	1	1.1	3.3	11.0
720	1.09	1	1	2.1	6.3	21.0
730	1.14	1	1	3.1	9.3	31.0
740	1.20	1	1.2	4.1	12.0	41.0
750	1.25	1	1.5	5.0	15.0	50.0
760	1.31	1	1.8	6.0	18.0	60.0
770	1.37	1	2.1	7.0	21.0	70.0
780	1.43	1	2.4	8.0	24.0	80.0
790	1.50	1	2.7	9.0	27.0	90.0
800	1.56	1	3.0	10.0	30.0	100.0
850	1.95	1	3.0	10.0	30.0	100.0
900	2.44	1	3.0	10.0	30.0	100.0
950	3.05	1	3.0	10.0	30.0	100.0
1000	3.82	1	3.0	10.0	30.0	100.0
1050	4.78	1	3.0	10.0	30.0	100.0
1060	5.00	1	3.0	10.0	30.0	100.0
1100	5.00	1	3.0	10.0	30.0	100.0
1400	5.00	1	3.0	10.0	30.0	100.0
1500	1.0	1.0				
1540	100.0*					
1600	1.0					
$1.0\text{X}10^6$	1.0					

* The factor $k_1 = 100.0$ when $t \leq 10^{-7}$, and $k_1 = 1.0$ when $t > 10^{-7}$

Note: The variable (t) is the magnitude of the sampling interval in units of seconds.

TABLE VI

ACCESSIBLE EMISSION LIMITS FOR COLLATERAL RADIATION FROM LASER PRODUCTS

1. Accessible emission limits for collateral radiation having wavelengths greater than 180 nanometers but less than or equal to 1.0×10^{6} nanometers are identical to the accessible emission limits of Class I laser radiation, as determined from Tables I and IV in this paragraph.

i. In the wavelength range of less than or equal to 400 nanometers, for all emission durations;

ii. In the wavelength range of greater than 400 nanometers, for all emission durations less than or equal to 1×10^{3} seconds and, when applicable under paragraph (f)(8) of this section, for all emission durations.

2. Accessible emission limit for collateral radiation within the x-ray range of wavelengths is 0.5 milliroentgen in an hour, averaged over a cross-section parallel to the external surface of the product, having an area of 10 square centimeters with no dimension greater than 5 centimeters.

(1) *Beam of a single wavelength.* Laser or collateral radiation of a single wavelength exceeds the accessible emission limits of a class if its accessible emission level is greater than the accessible emission limit of that class within any of the ranges of emission duration specified in Tables I, II-A, II, III-A, and III-B of this paragraph.

(2) *Beam of multiple wavelengths in same range.* Laser or collateral radiation having two or more wavelengths within any one of the wavelength ranges specified in Tables I, II-A, II, III-A, and III-B of this paragraph exceeds the accessible emission limits of a class if the sum of the ratios of the accessible emission level to the corresponding accessible emission limit at each such wavelength is greater than unity for that combination of emission duration and wavelength distribution which results in the maximum sum.

(3) *Beam with multiple wavelengths in different ranges.* Laser or collateral radiation having wavelengths within two or more of the wavelength ranges specified in Tables I, II-A, II, III-A, and III-B of this paragraph exceeds the accessible emission limits of a class if it exceeds the applicable limits within any one of those wavelength ranges. This determination is made for each wavelength range in accordance with paragraph (d) (1) or (2) of this section.

(4) *Class I dual limits.* Laser or collateral radiation in the wavelength range of greater than 400 nm but less than or equal to 1.400 nm exceeds the accessible emission limits of Class I if it exceeds both:

(i) The Class I accessible emission limits for radiant energy within any range of emission duration specified in Table I of this paragraph, and

(ii) The Class I accessible emission limits for integrated radiance within any range of emission duration specified in Table I of this paragraph.

(e) *Tests for determination of compliance*—(1) *Tests for certification.* Tests on which certification under § 1010.2 is based shall account for all errors and statistical uncertainties in the measurement process. Because compliance with the standard is required for the useful life of a product such tests shall also account for increases in emission and degradation in radiation safety with age.

(2) *Test conditions.* Except as provided in § 1010.13, tests for compliance with each of the applicable requirements of this section and § 1040.11 shall be made during operation, maintenance, or service as appropriate:

(i) Under those conditions and procedures which maximize the accessible emission levels, including start-up, stabilized emission, and shut-down of the laser product; and

(ii) With all controls and adjustments listed in the operation, maintenance, and service instructions adjusted in combination to result in the maximum accessible emission level of radiation; and

(iii) At points in space to which human access is possible in the product configuration which is necessary to determine compliance with each requirement, e.g., if operation may require removal of portions of the protective housing and defeat of safety interlocks, measurements shall be made at points accessible in that product configuration; and

(iv) With the measuring instrument detector so positioned and so oriented with respect to the laser product as to result in the maximum detection of radiation by the instrument; and

(v) For a laser product other than a laser system, with the laser coupled to that type of laser energy source which is specified as compatible by the laser product manufacturer and which produces the maximum emission level of accessible radiation from that product.

(3) *Measurement parameters.* Accessible emission levels of laser and collateral radiation shall be based upon the following measurements as appropriate, or their equivalent:

(i) For laser products intended to be used in a locale where the emitted laser radiation is unlikely to be viewed with optical instruments, the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1 X 10^{-3} steradian with collimating optics of 5 diopters or less. For scanned laser radiation, the direction of the solid angle of acceptance shall change as needed to maximize detectable radiation, with an angular speed of up to 5 radians/second. A 50 millimeter diameter aperture stop with the same collimating optics and acceptance angle stated above shall be used for all other laser products (except that a 7 millimeter diameter aperture stop shall be used in the measurement of scanned laser radiation emitted by laser products manufactured on or before August 20, 1986.

(ii) The irradiance (W cm^{-2}) or radiant exposure (J cm^{-2} equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and, for irradiance, within a circular solid angle of acceptance of 1 x 10^{-3} steradian with collimating optics of 5 diopters or less, divided by the area of the aperture stop (cm^{-2}).

(iii) The radiance (W cm^{-2} sr^{-1}) or integrated radiance (J cm^{-2} sr^{-1}) equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1 X 10^{-3} steradian with collimating optics of 5 diopters or less, divided by that solid angle (sr) and by the area of the aperture stop (cm^{-2}).

(f) *Performance requirements*—(1) *Protective housing.* Each laser product shall have a protective housing that prevents human access during operation to laser and collateral radiation that exceed the limits of Class I and Table VI, respectively, wherever and whenever such human access is not necessary for the product to perform its intended function. Wherever and whenever human access to laser radiation levels that exceed the limits of Class I is necessary, these levels shall not exceed the limits of the lowest class necessary to perform the intended function(s) of the product.

(2) *Safety interlocks.* (i) Each laser product, regardless of its class, shall be provided with at least one safety interlock for each portion of the protective housing which is designed to be removed or displaced during operation or maintenance, if removal or displacement of the protective housing could permit, in the absence of such interlock(s), human access to laser or collateral radiation in excess of the accessible emission limit applicable under paragraph (f)(1) of this section.

(ii) Each required safety interlock, unless defeated, shall prevent such human access to laser and collateral radiation upon removal or displacement of such portion of the protective housing

(iii) Either multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing shall be provided, if failure of a single interlock would allow;

(*a*) Human access to a level of laser radiation in excess of the accessible emission limits of Class IIIa; or

(*b*) Laser radiation in excess of the accessible emission limits of Class II to be emitted directly through the opening created by removal or displacement of the interlocked portion of the protective housing.

(iv) Laser products that incorporate safety interlocks designed to allow safety interlock defeat shall incorporate a means of visual or aural indication of interlock defeat. During interlock defeat, such indication shall be visible or audible whenever the laser product is energized, with and without the associated portion of the protective housing removed or displaced.

(v) Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated.

(3) *Remote interlock connector.* Each laser system classified as a Class IIIb or IV laser product shall incorporate a readily available remote interlock connector having an electrical potential difference of no greater than 130 root-mean-square volts between terminals. When the terminals of the connector are not electrically joined, human access to all laser and collateral radiation from the laser product in excess of the accessible emission limits of Class I and Table VI shall be prevented.

(4) *Key control.* Each laser system classified as a Class IIIb or IV laser product shall incorporate a key-actuated master control. The key shall be removable and the laser shall not be operable when the key is removed.

(5) *Laser radiation emission indicator.* (i) Each laser system classified as

a Class II or IIIa laser product shall incorporate an emission indicator that provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I.

(ii) Each laser system classified as a Class IIIb or IV laser product shall incorporate an emission indicator which provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I, and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to the laser radiation.

(iii) For laser systems manufactured on or before August 20, 1986, if the laser and laser energy source are housed separately and can be operated at a separation distance of greater than 2 meters, both laser and laser energy source shall incorporate an emission indicator as required in accordance with paragraph (f)(5) (i) or (ii) of this section. For laser systems manufactured after August 20, 1986, each separately housed laser and operation control of a laser system that regulates the laser or collateral radiation emitted by a product during operation shall incorporate an emission indicator as required in accordance with paragraph (f)(5) (i) or (ii) of this section, if the laser or operation control can be operated at a separation distance greater than 2 meters from any other separately housed portion of the laser product incorporating an emission indicator.

(iv) Any visible signal required by paragraph (f)(5) (i) or (ii) of this section shall be clearly visible through protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation.

(v) Emission indicators required by paragraph (f)(5) (i) or (ii) of this section shall be located so that viewing does not require human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI.

(6) *Beam attenuator.* (i) Each laser system classified as a Class II, III, or IV laser product shall be provided with one or more permanently attached means, other than laser energy source switch(es), electrical supply main connectors, or the key-actuated master control, capable of preventing access by any part of the human body to all laser and collateral radiation in excess of the accessible emission limits of Class I and Table VI.

(ii) If the configuration, design, or function of the laser product would make unnecessary compliance with the requirement in paragraph (f)(6)(i) of this section, the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, may, upon written application by the manufacturer, approve alternate means to accomplish the radiation protection provided by the beam attenuator.

(7) *Location of controls.* Each Class IIa, II, III, or IV laser product shall have operational and adjustment controls located so that human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI is unnecessary for operation or adjustment of such controls.

(8) *Viewing optics.* All viewing optics, viewports, and display screens incorporated into a laser product, regardless of its class, shall limit the levels of laser and collateral radiation accessible to the human eye by means of such viewing optics, viewports, or display screens during operation or maintenance to less than the accessible emission limits of Class I and Table VI. For any shutter or variable attenuator incorporated into such viewing optics, viewports, or display screens, a means shall be provided:

(i) To prevent access by the human eye to laser and collateral radiation in excess of the accessible emission limits of Class I and Table VI whenever the shutter is opened or the attenuator varied.

(ii) To preclude, upon failure of such means as required in paragraph (f)(8)(i) of this section, opening the shutter or varying the attenuator when access by the human eye is possible to laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI.

(9) *Scanning safeguard.* Laser products that emit accessible scanned laser radiation shall not, as a result of any failure causing a change in either scan

velocity or amplitude, permit human access to laser radiation in excess of:

(i) The accessible emission limits of the class of the product, or

(ii) The accessible emission limits of the class of the scanned laser radiation if the product is Class IIIb or IV and the accessible emission limits of Class IIIa would be exceeded solely as result of such failure.

(10) *Manual reset mechanism.* Each laser system manufactured after August 20, 1986, and classified as a Class IV laser product shall be provided with a manual reset to enable resumption of laser radiation emission after interruption of emission caused by the use of a remote interlock or after an interruption of emission in excess of 5 seconds duration due to the unexpected loss of main electrical power.

(g) *Labeling requirements.* In addition to the requirements of §§ 1010.2 and 1010.3, each laser product shall be subject to the applicable labeling requirements of this paragraph.

(1) *Class IIa and II designations and warnings.* (i) Each Class IIa laser product shall have affixed a label bearing the following wording: "Class IIa Laser Product—Avoid Long-Term Viewing of Direct Laser Radiation."

(ii) Each Class II laser product shall have affixed a label bearing the warning logotype A (Figure 1 in this paragraph) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—DO NOT STARE INTO BEAM"; and

[Position 3 on the logotype]

"CLASS II LASER PRODUCT".

WARNING LOGOTYPE A

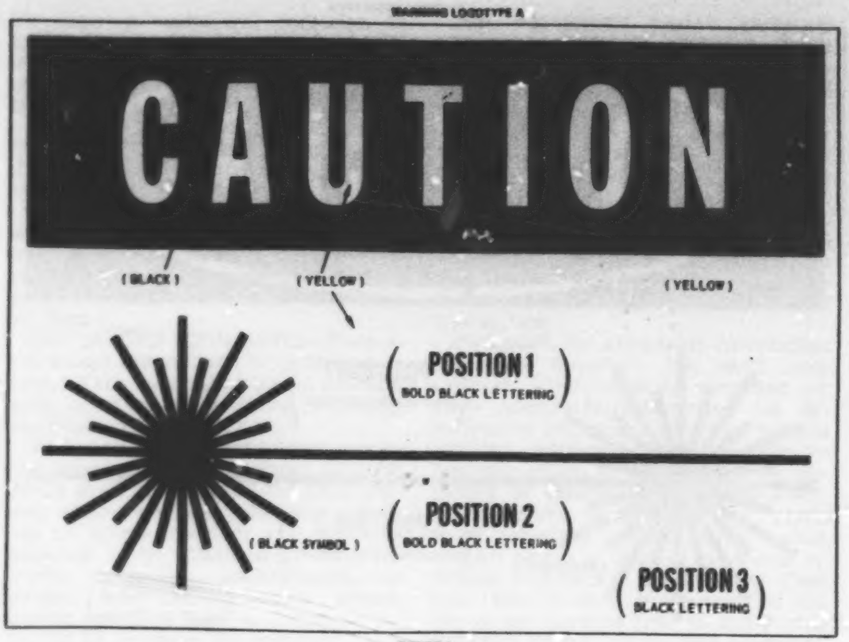
CAUTION
(BLACK)
(YELLOW)
(YELLOW)
POSITION 1
BOLD BLACK LETTERING
(BLACK SYMBOL)
POSITION 2
BOLD BLACK LETTERING
POSITION 3
BLACK LETTERING

FIGURE 1

(2) *Class IIIa and IIIb designations and warnings.* (i) Each Class IIIa laser product with an irradiance less than or equal to 2.5×10^{-3} W cm^{2-} shall have affixed a label bearing the warning logotype A (Figure 1 of paragraph (g)(1)(ii) of this section) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS"; and,

[Position 3 on the logotype]

"CLASS IIIa LASER PRODUCT".

(ii) Each Class IIIa laser product with an irradiance greater than 2.5×10^{-3} W cm^{-2} shall have affixed a label bearing the warning logotype B (Figure 2 in this paragraph) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—AVOID DIRECT EYE EXPOSURE"; and,

[Position 3 on the logotype]

"CLASS IIIa LASER PRODUCT".

WARNING LOGOTYPE B

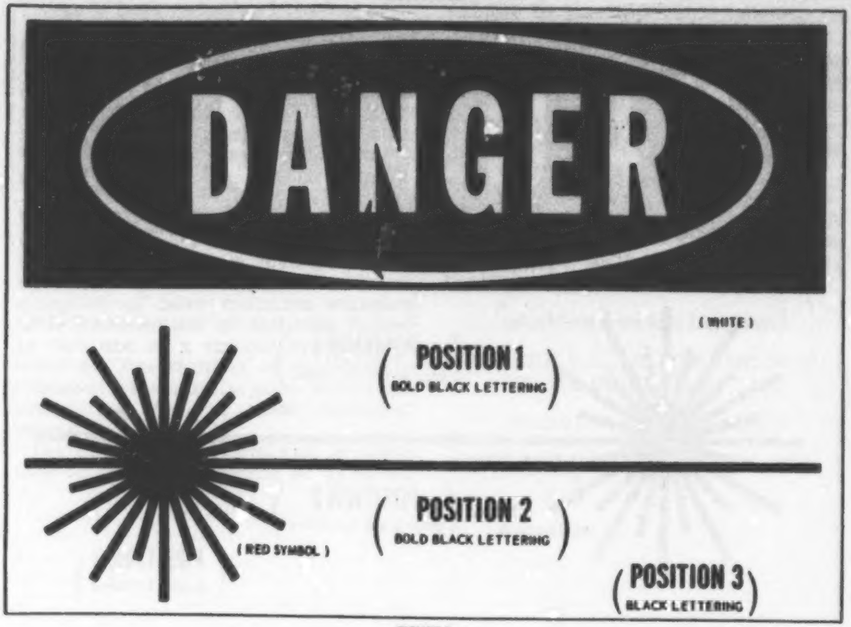

FIGURE 2

(iii) Each Class IIIb laser product shall have affixed a label bearing the warning logotype B (Figure 2 of paragraph (g)(2)(ii) of this section) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—AVOID DIRECT EXPOSURE TO BEAM"; and,

[Position 3 on the logotype]

"CLASS IIIb LASER PRODUCT".

(3) *Class IV designation and warning.* Each Class IV laser product shall have affixed a label bearing the warning logotype B (Figure 2 of paragraph (g)(2)(ii) of this section), and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION"; and,

[Position 3 on the logotype]

"CLASS IV LASER PRODUCT".

(4) *Radiation output information on warning logotype.* Each Class II, III, and IV laser product shall state in appropriate units, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength(s).

(5) *Aperture label.* Each laser product, except medical laser products and Class IIa laser products, shall have affixed, in close proximity to each aperture through which is emitted accessi-

ble laser or collateral radiation in excess of the accessible emission limits of Class I and Table VI of paragraph (d) of this section, a label(s) bearing the following wording as applicable.

(i) "AVOID EXPOSURE—Laser radiation is emitted from this aperture," if the radiation emitted through such aperture is laser radiation.

(ii) "AVOID EXPOSURE—Hazardous electromagnetic radiation is emitted from this aperture," if the radiation emitted through such aperture is collateral radiation described in Table VI, item 1.

(iii) "AVOID EXPOSURE—Hazardous x-rays are emitted from this aperture," if the radiation emitted through such aperture is collateral radiation described in Table VI, item 2.

(6) *Labels for noninterlocked protective housings.* For each laser product, labels shall be provided for each portion of the protective housing which has no safety interlock and which is designed to be displaced or removed during operation, maintenance, or service, and thereby could permit human access to laser or collateral radiation in excess of the limits of Class I and Table VI. Such labels shall be visible on the protective housing prior to displacement or removal of such portion of the protective housing and visible on the product in close proximity to the opening created by removal or displacement of such portion of the protective housing, and shall include the wording:

(i) "CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM." for Class II accessible laser radiation.

(ii) "CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS." for Class IIIa accessible laser radiation with an irradiance less than or equal to 2.5×10^{-3} W cm^{-2}.

(iii) "DANGER—Laser radiation when open. AVOID DIRECT EYE EXPOSURE." for Class IIIa accessible laser radiation with an irradiance greater than 2.5×10^{-3} W cm^{-2}.

(iv) "DANGER—Laser radiation when open. AVOID DIRECT EXPOSURE TO BEAM." for Class IIIb accessible laser radiation.

(v) "DANGER—Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for Class IV accessible laser radiation.

(vi) "CAUTION—Hazardous electromagnetic radiation when open." for collateral radiation in excess of the accessible emission limits in Table VI, item 1 of paragraph (d) of this section.

(vii) "CAUTION—Hazardous x-rays when open." for collateral radiation in excess of the accessible emission limits in Table VI, item 2 of paragraph (d) of this section.

(7) *Labels for defeatably interlocked protective housings.* For each laser product, labels shall be provided for each defeatably interlocked (as described in paragraph (f)(2)(iv) of this section) portion of the protective housing which is designed to be displaced or removed during operation, maintenance, or service, and which upon interlock defeat could permit human access to laser or collateral radiation in excess of the limits of Class I or Table VI. Such labels shall be visible on the product prior to and during interlock defeat and in close proximity to the opening created by the removal or displacement of such portion of the protective housing, and shall include the wording:

(i) "CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM." for Class II accessible laser radiation.

(ii) "CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS." for Class IIIa accessible laser radiation with an irradiance less than or equal to 2.5×10^{-3} W cm^{-2}.

(iii) "DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EYE EXPOSURE." for Class IIIa accessible laser radiation when an irradiance greater than 2.5×10^{-3} W cm^{-2}.

(iv) "DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EXPOSURE TO BEAM." for Class IIIb accessible laser radiation.

(v) "DANGER—Laser radiation when open and interlock defeated. AVOID EYE OR SKIN EXPOSURE

TO DIRECT OR SCATTERED RADIATION." for Clas IV accessible laser radiation.

(vi) "CAUTION—Hazardous electromagnetic radiation when open and interlock defeated." for collateral radiation in excess of the accessible emission limits in Table VI. item 1 of paragraph (d) of this section.

(vii) "CAUTION—Hazardous x-rays when open and interlock defeated." for collateral radiation in excess of the accesible emission limits in Table VI. item 2 of paragraph (d) of this section.

(8) *Warning for visible and/or invisible radiation.* On the labels specified in this paragraph, if the laser or collateral radiation referred to is:

(i) Invisible radiation, the word "invisible" shall appropriately precede the word "radiation"; or

(ii) Visible and invisible radiation, the words "visible and invisible" or "visible and/or invisible" shall appropriately precede the word "radiation."

(iii) Visible laser radiation only, the phrase "laser light" may replace the phrase "laser radiation."

(9) *Positioning of labels.* All labels affixed to a laser product shall be positioned so as to make unnecessary, during reading, human exposure to laser radiation in excess of the accessible emission limits of Class I radiation or the limits of collateral radiation established to Table VI of paragraph (d) of this section.

(10) *Label specifications.* Labels required by this section and § 1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, or service, as appropriate. If the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, on the Director's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s) or alternate wording for such label(s) as applicable.

(h) *Informational requirements*—(1) *User information.* Manufacturers of laser products shall provide as an integral part of any user instruction or operation manual which is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each laser product:

(i) Adequate instructions for assembly, operation, and maintenance, including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11.

(ii) A statement of the magnitude, in appropriate units, of the pulse durations(s), maximum radiant power and, where applicable, the maximum radiant energy per pulse of the accessible laser radiation detectable in each direction in excess of the accessible emission limits in Table I of paragraph (d) of this section determined under paragraph (e) of this section.

(iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and § 1040.11 to be affixed to the laser product or provided with the laser product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 of paragraph (g)(1)(ii) or Figure 2 or paragragh (g)(2)(ii) of this section). The corresponding position of each label affixed to the product shall be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in which they were supplied shall be provided.

(iv) A listing of all controls, adjustments, and procedures for operation and maintenance, including the warning "Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure."

(v) In the case of laser products other than laser systems, a statment of the compatibility requirements for a laser energy source that will assure compliance of the laser product with this section and § 1040.11.

(vi) In the case of laser products classified with a 7 millimeter diameter aperture stop as provided in paragraph (e)(3)(i) of this section, if the use of a 50 millimeter diameter aperture stop would result in a higher classification of the product, the following warning shall be included in the user information: "CAUTION—The use of optical instruments with this product will increase eye hazard."

(2) *Purchasing and servicing information.* Manufacturers of laser products shall provide or cause to be provided:

(i) In all catalogs, specification sheets, and descriptive brochures pertaining to each laser product, a legible reproduction (color optional) of the class designation and warning required by paragraph (g) of this section to be affixed to that product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 of paragraph (g)(1)(ii) or Figure 2 of paragraph (g)(2)(ii) of this section).

(ii) To servicing dealers and distributors and to others upon request at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model, including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11; and in all such service instructions, a listing of those controls and procedures that could be utilized by persons other than the manufacturers or the manufacturer's agents to increase accessible emission levels of radiation and a clear description of the location of displaceable portions of the protective housing that could allow human access to laser or collateral radiation in excess of the accessible emission limits in Tables I, II-A, II, III-A, III-B, and VI of paragraph (d) of this section. The instructions shall include protective procedures for service personnel to avoid exposure to levels of laser and collateral radiation known to be hazardous for each procedure or sequence of procedures to be accomplished, and legible reproductions (color optional) of required labels and hazard warnings.

(i) *Modification of a certified product.* The modification of a laser product, previously certified under § 1010.2, by any person engaged in the business of manufacturing, assembling, or modifying laser products shall be construed as manufacturing under the act if the modification affects any aspect of the product's performance or intended function(s) for which this section and § 1040.11 have an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the product in accordance with the provisions of §§ 1010.2. and 1010.3.

(The information collection requirements contained in paragraph (a)(3)(ii) were approved by the Office of Management and Budget under control number 0910-0176)

[50 FR 33688, Aug. 20, 1985; 50 FR 42156, Oct. 18, 1985]

§ 1040.11 Specific purpose laser products.

(a) *Medical laser products.* Each medical laser product shall comply with all of the applicable requirements of § 1040.10 for laser products of its class. In addition, the manufacturer shall:

(1) Incorporate in each Class III or IV medical laser product a means for the measurement of the level of that laser radiation intended for irradiation of the human body. Such means may have an error in measurement of no more than 20 percent when calibrated in accordance with paragraph (a)(2) of this section. Indication of the measurement shall be in International System Units. The requirements of this paragraph do not apply to any laser radiation that is all of the following:

(i) Of a level less than the accessible limits of Class IIIa; and

(ii) Used for relative positioning of the human body; and

(iii) Not used for irradiation of the human eye for ophthalmic purposes.

(2) Supply with each Class III or IV medical laser product instructions specifying a procedure and schedule for calibration of the measurement system required by paragraph (a)(1) of this section.

(3) Affix to each medical laser product, in close proximity to each aperture through which is emitted accessible laser radiation in excess of the accessible emission limits of Class I, a label bearing the wording: "Laser aperture."

(b) *Surveying, leveling, and alignment laser products.* Each surveying, leveling, or alignment laser product shall comply with all of the applicable requirements of § 1040.10 for a Class I, IIa, II or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class IIIa.

(c) *Demonstration laser products.* Each demonstration laser product shall comply with all of the applicable requirements of § 1040.10 for a Class I, IIa, II, or IIIa laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class IIa, Class II, or Class IIIa.

[50 FR 33702, Aug. 20, 1985]

§ 1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

(a) *Applicability.* (1) The provisions of this section, as amended, are applicable as specified herein to the following products manufactured on or after September 8, 1986.

(i) Any sunlamp product.

(ii) Any ultraviolet lamp intended for use in any sunlamp product.

(2) Sunlamp products and ultraviolet lamps manufactured on or after May 7, 1980, but before September 8, 1986, are subject to the provisions of this section as published in the FEDERAL REGISTER of November 9, 1979 (44 FR 65357).

(b) *Definitions.* As used in this section the following definitions apply:

(1) "Exposure position" means any position, distance, orientation, or location relative to the radiating surfaces of the sunlamp product at which the user is intended to be exposed to ultraviolet radiation from the product, as recommended by the manufacturer.

(2) "Intended" means the same as "intended uses" in § 801.4.

(3) "Irradiance" means the radiant power incident on a surface at a specified location and orientation relative to the radiating surface divided by the area of the surface, as the area becomes vanishingly small, expressed in units of watts per square centimeter (W/cm^2).

(4) "Maximum exposure time" means the greatest continuous exposure time interval recommended by the manufacturer of the product.

(5) "Maximum timer interval" means the greatest time interval setting on the timer of a product.

(6) "Protective eyewear" means any device designed to be worn by users of a product to reduce exposure of the eyes to radiation emitted by the product.

(7) "Spectral irradiance" means the irradiance resulting from radiation within a wavelength range divided by the wavelength range as the range becomes vanishingly small, expressed in units of watts per square centimeter per nanometer ($W/(cm^2/nm)$).

(8) "Spectral transmittance" means the spectral irradiance transmitted through protective eyewear divided by the spectral irradiance incident on the protective eyewear.

(9) "Sunlamp product" means any electronic product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning.

(10) "Timer" means any device incorporated into a product that terminates radiation emission after a preset time interval.

(11) "Ultraviolet lamp" means any lamp that produces ultraviolet radiation in the wavelength interval of 200 to 400 nanometers in air and that is intended for use in any sunlamp product.

(c) *Performance requirements*—(1) *Irradiance ratio limits.* For each sunlamp product and ultraviolet lamp, the ratio of the irradiance within the wavelength range of greater than 200 nanometers through 260 nanometers to the irradiance within the wavelength range of greater than 260 nanometers through 320 nanometers may not exceed 0.003 at any distance and direction from the product or lamp.

(2) *Timer system.* (i) Each sunlamp product shall incorporate a timer system with multiple timer settings adequate for the recommended exposure time intervals for different exposure positions and expected results of the products as specified in the label required by paragraph (d) of this section.

(ii) The maximum timer interval(s) may not exceed the manufacturer's recommended maximum exposure time(s) that is indicated on the label required by paragraph (d)(1)(iv) of this section.

(iii) No timer interval may have an error greater than 10 percent of the maximum timer interval of the product.

(iv) The timer may not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when emission from the sunlamp product has been terminated.

(v) The timer requirements do not preclude a product from allowing a user to reset the timer before the end of the preset time interval.

(3) *Control for termination of radiation emission.* Each sunlamp product shall incorporate a control on the product to enable the person being exposed to terminate manually radiation emission from the product at any time without disconnecting the electrical plug or removing the ultraviolet lamp.

(4) *Protective eyewear.* (i) Each sunlamp product shall be accompanied by the number of sets of protective eyewear that is equal to the maximum number of persons that the instructions provided under paragraph (e)(1)(ii) of this section recommend to be exposed simultaneously to radiation from such product.

(ii) The spectral transmittance to the eye of the protective eyewear required by paragraph (c)(4)(i) of this section shall not exceed a value of 0.001 over the wavelength range of greater than 200 nanometers 320 nanometers and an value of 0.01 over the wavelength range of greater than 320 nanometers through 400 nanometers, and shall be sufficient over the wavelength greater than 400 nanometers to enable the user to see clearly enough to reset the timer.

(5) *Compatibility of lamps.* An ultraviolet lamp may not be capable of insertion and operation in either the "single-contact medium screw" or the "double-contact medium screw" lampholders described in American National Standard C81.10-1976, Specifications for Electric Lamp Bases and Holders—Screw-Shell Types, which is incorporated by reference. Copies are available from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(d) *Label requirements.* In addition to the labeling requirements in Part 801 and the certification and identification requirements of §§ 1010.2 and 1010.3, each sunlamp product and ultraviolet lamp shall be subject to the labeling requirements prescribed in this paragraph and paragraph (e) of this section.

(1) *Labels for sunlamp products.* Each sunlamp product shall have a label(s) which contains:

(i) A warning statement with the words "DANGER—Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from the use of this product."

(ii) Recommended exposure position(s). Any exposure position may be expressed either in terms of a distance specified both in meters and in feet (or in inches) or through the use of markings or other means to indicate clearly the recommended exposure position.

(iii) Directions for achieving the recommended exposure position(s) and a warning that the use of other positions may result in overexposure.

(iv) A recommended exposure schedule including duration and spacing of sequential exposures and maximum exposure time(s) in minutes.

(v) A statement of the time it may take before the expected results appear.

(vi) Designation of the ultraviolet lamp type to be used in the product.

(2) *Labels for ultraviolet lamps.* Each ultraviolet lamp shall have a label which contains:

(i) The words "Sunlamp—DANGER—Ultraviolet radiation. Follow instructions."

(ii) The model identification.

(iii) The words "Use ONLY in fixture equipped with a timer."

(3) *Label specifications.* (i) Any label prescribed in this paragraph for sunlamp products shall be permanently affixed or inscribed on an exterior surface of the product when fully assembled for use so as to be legible and readily accessible to view by the person being exposed immediately before the use of the product.

(ii) Any label prescribed in this paragraph for ultraviolet lamps shall be permanently affixed or inscribed on the product so as to be legible and readily accessible to view.

(iii) If the size, configuration, design, or function of the sunlamp product or ultraviolet lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, or would render the required label unnecessary, the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, on the Center's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s), alternate wording for such label(s), or deletion, as applicable.

(iv) In lieu of permanently affixing or inscribing tags or labels on the ultraviolet lamp as required by §§ 1010.2(b) and 1010.3(a), the manfacturer of the ultraviolet lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the lamp, if the name of the manufacturer and month and year of manufacture are permanently affixed or inscribed on the exterior surface of the ultraviolet lamp so as to be legible and readily accessible to view. The name of the manufacturer and month and year of manufacture affixed or inscribed on the exterior surface of the lamp may be expressed in code or symbols, if the manufacturer has previously supplied the Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, with the key to such code or symbols and the location of the coded information or symbols on the ultraviolet lamp. The label or tag affixed or inscribed on the lamp packaging may provide either the month and year of manufacture without abbreviation, or information to allow the date to be readily decoded.

(v) A label may contain statements or illustrations in addition to those required by this paragraph if the additional statements are not false or misleading in any particular; e.g., if they do not diminish the impact of the required statements; and are not prohibited by this chapter.

(e) *Instructions to be provided to users.* Each manufacturer of a sunlamp product and ultraviolet lamp shall provide or cause to be provided to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, adequate instructions for use to avoid or to minimize potential injury to the user, including the following technical and safety information as applicable:

(1) *Sunlamp products.* The users' instructions for a sunlamp product shall contain:

(i) A reproduction of the label(s) required in paragraph (d)(1) of this section prominently displayed at the beginning of the instructions.

(ii) A statement of the maximum number of people who may be exposed to the product at the same time and a warning that only that number of protective eyewear has been provided.

(iii) Instructions for the proper operation of the product including the function, use, and setting of the timer and other controls, and the use of protective eyewear.

(iv) Instructions for determining the correct exposure time and schedule for persons according to skin type.

(v) Instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the product, including compatible protective eyewear, ultraviolet lamps, timers, reflectors, and filters, and which will, if installed or used as instructed, result in continued compliance with the standard.

(2) *Ultraviolet lamps.* The users' instructions for an ultraviolet lamp not accompanying a sunlamp product shall contain:

(i) A reproduction of the label(s) required in paragraphs (d)(1)(i) and (2) of this section, prominently displayed at the beginning of the instructions.

(ii) A warning that the instructions accompanying the sunlamp product should always be followed to avoid or to minimize potential injury.

(iii) A clear identification by brand and model designation of all lamp models for which replacement lamps are promoted, if applicable.

(f) *Test for determination of compliance.* Tests on which certification pursuant to § 1010.2 is based shall account for all errors and statistical uncertainties in the process and, wherever applicable, for changes in radiation emission or degradation in radiation safety with age of the product. Measurements for certification purposes shall be made under those operational conditions, lamp voltage, current, and position as recommended by the manufacturer. For these measurements, the measuring instrument shall be positioned at the recommended exposure position and so oriented as to result in the maximum detection of the radiation by the instrument.

(The information collection requirements contained in paragraphs (d) and (e) were approved by the Office of Management and Budget under control number 0910-0195)

[50 FR 36550, Sept. 6, 1985]

§ 1040.30 High-intensity mercury vapor discharge lamps.

(a) *Applicability.* The provisions of this section apply to any high-intensity mercury vapor discharge lamp that is designed, intended, or promoted for illumination purposes and is manufactured or assembled after March 7, 1980, except as described in paragraph (d)(1)(ii) of this section.

(b) *Definitions.* (1) "High-intensity mercury vapor discharge lamp" means any lamp including any "mercury vapor" and "metal halide" lamp, with the exception of the tungsten filament self-ballasted mercury vapor lamp, incorporating a high-pressure arc discharge tube that has a fill consisting primarily of mercury and that is contained within an outer envelope.

(2) "Advertisement" means any catalog, specification sheet, price list, and any other descriptive or commercial brochure and literature, including videotape and film, pertaining to high-intensity mercury vapor discharge lamps.

(3) "Packaging" means any lamp carton, outer wrapping, or other means of containment that is intended for the storage, shipment, or display of a high-intensity mercury vapor lamp and is intended to identify the contents or recommend its use.

(4) "Outer envelope" means the lamp element, usually glass, surrounding a high-pressure arc discharge tube, that, when intact, attenuates the emission of shortwave ultraviolet radiation.

(5) "Shortwave ultraviolet radiation" means ultraviolet radiation with wavelengths shorter than 320 nanometers.

(6) "Cumulative operating time" means the sum of the times during which electric current passes through the high-pressure arc discharge.

(7) "Self-extinguishing lamp" means a high-intensity mercury vapor discharge lamp that is intended to comply with the requirements of paragraph (d)(1) of this section as applicable.

(8) "Reference ballast" is an inductive reactor designed to have the operating characteristics as listed in Section 7 in the American National Standard Specifications for High-Intensity Discharge Lamp Reference

Ballasts (ANSI C82.5-1977)[1] or its equivalent.

(c) *General requirements for all lamps.* (1) Each high-intensity mercury vapor discharge lamp shall:

(i) Meet the requirements of either paragraph (d) or paragraph (e) of this section; and

(ii) Be permanently labeled or marked in such a manner that the name of the manufacturer and the month and year of manufacture of the lamp can be determined on an intact lamp and after the outer envelope of the lamp is broken or removed. The name of the manufacturer and month and year of manufacture may be expressed in code or symbols, provided the manufacturer has previously supplied the Director, Bureau of Radiological Health, with the key to the code or symbols and the location of the coded information or symbols on the lamp.

(2) In lieu of permanently affixing or inscribing tags or labels on the product as required by §§ 1010.2(b) and 1010.3(a) of this chapter, the manufacturer of any high-intensity mercury vapor discharge lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the applicable lamp.

(d) *Requirements for self-extinguishing lamps*—(1) *Maximum cumulative operating time.* (i) Each self-extinguishing lamp manufactured after March 7, 1980 shall cease operation within a cumulative operating time not to exceed 15 minutes following complete breakage or removal of the outer envelope (with the exception of fragments extending 50 millimeters or less from the base shell); and

(ii) Each self-extinguishing lamp manufactured after September 7, 1981, shall cease operation within a cumulative operating time not to exceed 15 minutes following breakage or removal of at least 3 square centimeters of contiguous surface of the outer envelope.

(2) *Lamp labeling.* Each self-extinguishing lamp shall be clearly marked with the letter "T" on the outer envelope and on another part of the lamp in such a manner that it is visible after the outer envelope of the lamp is broken or removed.

(3) *Lamp packaging.* Lamp packaging for each self-extinguishing lamp shall clearly and prominently display:

(i) The letter "T"; and

(ii) The words "This lamp should self-extinguish within 15 minutes after the outer envelope is broken or punctured. If such damage occurs, TURN OFF AND REMOVE LAMP to avoid possible injury from hazardous shortwave ultraviolet radiation."

(e) *Requirements for lamps that are not self-extinguishing lamps*—(1) *Lamp labeling.* Any high-intensity mercury vapor discharge lamp that does not comply with paragraph (d)(1) of this section shall be clearly and legibly marked with the letter "R" on the outer envelope and on another part of the lamp in such a manner that it is visible after the outer envelope of the lamp is broken or removed.

(2) *Lamp packaging.* Lamp packaging for each high-intensity mercury vapor discharge lamp that does not comply with paragraph (d)(1) of this section shall clearly and prominently display:

(i) The letter "R"; and

(ii) The words "WARNING: This lamp can cause serious skin burn and eye inflammation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Lamps that will automatically extinguish when the outer envelope is broken or punctured are commercially available."

(3) *Lamp advertisement.* Advertising for any high-intensity mercury vapor discharge lamp that does not comply with paragraph (d)(1) of this section shall prominently display the following wording: "WARNING: This lamp can cause serious skin burn and eye inflammation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Lamps that will automatical-

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[1] Copies are available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

ly extinguish when the outer envelope is broken or punctured are commercially available."

(f) *Test conditions.* Any high-intensity mercury vapor discharge lamp under test for compliance with the requirements set forth in paragraph (d)(1) of this section shall be started and operated under the following conditions as applicable:

(1) Lamp voltage, current, and orientation shall be those indicated or recommended by the manufacturer for operation of the intact lamp.

(2) The lamp shall be operated on a reference ballast.

(3) The lamp shall be started in air that has a temperature of 25±5° C. Heating and movement of the air surrounding the lamp shall be that produced by the lamp and ballast alone.

(4) If any test is performed in an enclosure, the enclosure shall be not less than 0.227 cubic meter (8 cubic feet).

(5) Any lamp designed to be operated only in a specific fixture or luminaire that the lamp manufacturer supplies or specifies shall be tested in that fixture or luminaire. Any other lamp shall be tested with no reflector or other surrounding material.

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f))

[44 FR 52195, Sept. 7, 1979]

PART 1050—PERFORMANCE STANDARDS FOR SONIC, INFRASONIC, AND ULTRASONIC RADIATION-EMITTING PRODUCTS

§ 1050.10 Ultrasonic therapy products.

(a) *Applicability.* The provisions of this section are applicable as specified herein to any ultrasonic therapy product for use in physical therapy manufactured on or after February 17, 1979.

(b) *Definitions.* The following definitions apply to words and phrases used in this section:

(1) "Amplitude modulated waveform" means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is greater than 1.05.

(2) "Applicator means that portion of a fully assembled ultrasonic therapy product that is designed to emit ultrasonic radiation and which includes one or more ultrasonic transducers and any associated housing.

(3) "Beam cross-section" means the surface in any plane consisting of the points at which the intensity is greater than 5 percent of the spatial-maximum intensity in that plane.

(4) "Beam nonuniformity ratio" means the ratio of the temporal-average spatial-maximum intensity to the temporal-average effective intensity.

(5) "Centroid of a surface" means the point whose coordinates are the mean values of the coordinates of the points of the surface.

(6) "Collimating applicator" means an applicator that does not meet the definition of a focusing applicator as specified in paragraph (b)(15) of this section and for which the ratio of the area of at least one beam cross-section, whose centroid is 12 centimeters from the centroid of the effective radiating surface, to the area of the effective radiating surface is less than two.

(7) "Continuous-wave waveform" means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is less than or equal to 1.05.

(8) "Diverging applicator" means an applicator that does not meet the definition of a collimating applicator or a focusing applicator as specified in paragraphs (b) (6) and (15) of this section.

(9) "Effective intensity" means the ratio of the ultrasonic power to the focal area for a focusing applicator. For all other applicators, the effective intensity is the ratio of the ultrasonic power to the effective radiating area. Effective intensity is expressed in watts per square centimeter (W cm^{-2}).

(10) "Effective radiating area" means the area consisting of all points of the effective radiating surface at which the intensity is 5 percent or more of the maximum intensity at the effective radiating surface, expressed in square centimeters (cm^2).

(11) "Effective radiating surface" means the surface consisting of all points 5 millimeters from the applicator face.

(12) "Focal area" means the area of the focal surface, expressed in square centimeters (cm^2).

(13) "Focal length" means the distance between the centroids of the effective radiating surface and the focal surface, for a focusing applicator, expressed in centimeters (cm).

(14) "Focal surface" means the beam cross-section with smallest area of a focusing applicator.

(15) "Focusing applicator" means an applicator in which the ratio of the area of the beam cross-section with the smallest area to the effective radiating area is less than one-half.

(16) "Generator" means that portion of a fully assembled ultrasonic therapy product that supplies electrical energy to the applicator. The generator may include, but is not limited to, a power supply, ultrasonic frequency oscillator, service controls, operation controls, and a cabinet to house these components.

(17) "Maximum beam nonuniformity ratio" means the maximum value of the beam nonuniformity ratio characteristic of a model of an ultrasonic therapy product.

(18) "Operation control" means any control used during operation of an ultrasonic therapy product that affects the ultrasonic radiation emitted by the applicator.

(19) "Pressure amplitude" means the instantaneous value of the modulating waveform, and is $p_1(t)$ in the expression for a pressure wave, $p(t)=p_1(t)\ p_2(t)$, where $p(t)$ is the instantaneous pressure, $p_1(t)$ is the modulating envelope, and $p_2(t)$ is the relative amplitude of the carrier wave normalized to a peak height of one. All are periodic functions of time, t, at any point in space. The period of $p_1(t)$ is greater than the period of $p_2(t)$.

(20) "Pulse duration" means a time interval, expressed in seconds, beginning at the first time the pressure amplitude exceeds the minimum pressure amplitude plus 10 percent of the difference between the maximum and minimum pressure amplitudes, and ending at the last time the pressure amplitude returns to this value.

(21) "Pulse repetition rate" means the repetition frequency of the waveform modulating the ultrasonic carrier wave expressed in pulses per second (pps).

(22) "Service control" means any control provided for the purpose of adjustment that is not used during operation and can affect the ultrasonic radiation emitted by the applicator, or can alter the calibration or accuracy of an indicator or operation control.

(23) "Ultrasonic frequency" means the frequency of the ultrasonic radiation carrier wave, expressed in Hertz (Hz), kilohertz (kHz), or megahertz (MHz).

(24) "Ultrasonic power" means the total power emitted in the form of ultrasonic radiation by the applicator averaged over each cycle of the ultrasonic radiation carrier wave, expressed in watts.

(25) "Ultrasonic therapy product" means:

(i) Any device intended to generate and emit ultrasonic radiation for therapeutic purposes at ultrasonic frequencies above 16 kilohertz (kHz); or

(ii) Any generator or applicator designed or specifically designated for use in a device as specified in paragraph (b)(25)(i) of this section.

(26) "Ultrasonic transducer" means a device used to convert electrical energy of ultrasonic frequency into ultrasonic radiation or vice versa.

(c) *Performance requirements.* The requirements of this paragraph are applicable to each ultrasonic therapy product as defined in paragraph (b)(25) of this section when the generator and applicator are designated or intended for use together, or to each generator when the applicator(s) intended for use with the generator does not contain controls that affect the functioning of the generator.

(1) *Ultrasonic power and intensity*—(i) *Continuous-wave waveform operation.* A means shall be incorporated to indicate the magnitudes of the temporal-average ultrasonic power and the temporal-average effective intensity when emission is of continuous-wave waveform. The error in the indication of the temporal-average ultra-

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sonic power shall not exceed ±20 percent for all emissions greater than 10 percent of the maximum emission.

(ii) *Amplitude-modulated waveform operation.* A means shall be incorporated to indicate the magnitudes of the temporal-maximum ultrasonic power and the temporal-maximum effective intensity when the emission is of amplitude-modulated waveform. The sum of the errors in the indications of the temporal-maximum ultrasonic power and the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity specified in paragraph (d)(3)(ii) of this section shall not exceed ±20 percent for all emissions greater than 10 percent of the maximum emission.

(2) *Treatment time.* A means shall be incorporated to enable the duration of emission of ultrasonic radiation for treatment to be preset and such means shall terminate emission at the end of the preset time. Means shall also be incorporated to enable termination of emission at any time. Means shall be incorporated to indicate the magnitude of the duration of emission (expressed in minutes) to within 0.5 minute of the preset duration of emission for setting less than 5 minutes, to within 10 percent of the preset duration of emission for settings of from 5 minutes to 10 minutes, and to within 1 minute of the preset duration of emission for settings greater than 10 minutes.

(3) *Pulse duration and repetition rate.* A means shall be incorporated for indicating the magnitudes of pulse duration and pulse repetition rate of the emitted ultrasonic radiation, if there are operation controls for varying these quantities.

(4) *Ultrasonic frequency.* A means shall be incorporated for indicating the magnitude of the ultrasonic frequency of the emitted ultrasonic radiation, if there is an operation control for varying this quantity.

(5) *Visual indicator.* A means shall be incorporated to provide a clear, distinct, and readily understood visual indicator when and only when electrical energy of appropriate ultrasonic frequency is being applied to the ultrasonic transducer(s).

(d) *Labeling requirements.* In addition to the labeling requirements in Part 801 and the requirements of §§ 1010.2 and 1010.3 of this chapter, each ultrasonic therapy product shall be subject to the applicable labeling requirements of this paragraph.

(1) *Operation controls.* Each operation control shall be clearly labeled identifying the function controlled and, where appropriate, the units of measure of that function. If a separate control and indicator are associated with the same function, then labeling the appropriate units of measure of that function is required for the indicator but not for the control.

(2) *Service controls.* Each service control that is accessible without displacement or removal of any part of the ultrasonic therapy product shall be clearly labeled identifying the function controlled and shall include the phrase "for service adjustment only."

(3) *Generators.* (i) Each generator shall bear a label that states: The brand name, model designation, and unique serial number or other unique identification so that it is individually identifiable; ultrasonic frequency (unless there is an operation control for varying this quantity); and type of waveform (continuous wave or amplitude modulated).

(ii) Generators employing amplitude-modulated waveforms shall also bear a label that provides the following information: Pulse duration and pulse repetition rate (unless there are operation controls for varying these quantities), an illustration of the amplitude-modulated waveform, and the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity. (If this ratio is a function of any operation control setting, then the range of the ratio shall be specified, and the waveform illustration shall be provided for the maximum value of this ratio.)

(4) *Applicators.* Each applicator shall bear a label that provides the following information:

(i) The brand name, model designation, and unique serial number or other unique identification so the applicator is individually identifiable;

(ii) A designation of the generator(s) for which the applicator is intended; and

(iii) The ultrasonic frequency, effective radiating area, maximum beam nonuniformity ratio, type of applicator (focusing, collimating, diverging), and for a focusing applicator the focal length and focal area.

(5) *Label specification.* Labels required by this paragraph shall be permanently affixed to or inscribed on the ultrasonic therapy product; they shall be legible and clearly visible. If the size, configuration, or design of the ultrasonic therapy product would preclude compliance with the requirements of this paragraph, the Director, Bureau of Radiological Health, may approve alternate means of providing such labels).

(e) *Tests for determination of compliance*—(1) *Tests for certification.* Tests on which certification pursuant to § 1010.2 of this chapter is based shall account for all measurement errors and uncertainties. Such tests shall also account for increases in emission and degradation in radiation safety that occur with age.

(2) *Test conditions.* Except as provided in § 1010.13 of this chapter, tests for compliance with each of the applicable requirements of this section shall be made:

(i) For all possible combinations of adjustments of the controls listed in the operation instructions.

(ii) With the ultrasonic radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30° C for measurements concerning the ultrasonic radiation.

(iii) With line voltage variations in the range of ±10 percent of the rated value specified by the manufacturer.

(3) *Measurement parameters.* Measurements for determination of the spatial distribution of the ultrasonic radiation field shall be made with a detector having dimensions of less than one wavelength in water or an equivalent measurement technique.

(f) *Informational requirements*—(1) *Servicing information.* The manufacturer of an ultrasonic therapy product shall provide or cause to be provided to servicing dealers and distributors, and to others upon request, at a cost not to exceed the cost of preparation and distribution adequate instructions for operations, service, and calibration, including a description of those controls and procedures that could be used to increase radiation emission levels, and a schedule of maintenance necessary to keep equipment in compliance with this section. The instructions shall include adequate safety precautions that may be necessary regarding ultrasonic radiation exposure.

(2) *User information.* The manufacturer of an ultrasonic therapy product shall provide as an integral part of any user instruction or operation manual that is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each ultrasonic therapy product, and to others upon request, at a cost not to exceed the cost of preparation and distribution:

(i) Adequate instructions concerning assembly, operation, safe use, any safety procedures and precautions that may be necessary regarding the use of ultrasonic radiation, and a schedule of maintenance necessary to keep the equipment in compliance with this section. The operation instructions shall include a discussion of all operation controls, and shall describe the effect of each control.

(ii) Adequate description of the spatial distribution of the ultrasonic radiation field and the orientation of the field with respect to the applicator. This will include a textual discussion with diagrams, plots, or photographs representative of the beam pattern. If there is more than one ultrasonic transducer in an applicator and their positions are not fixed relative of each other, then the description must specify the spatial distribution of the ultrasonic radiation field emitted by each ultrasonic transducer and present adequate examples of the combination field of the ultrasonic tranducers with regard to safe use. The description of the ultrasonic radiation field shall state that such description applies under conditions specified in paragraph (e)(2)(ii) of this section.

(iii) Adequate description, as appropriate to the product, of the uncertainties in magnitude expressed in terms of percentage error, of the ultrasonic frequency effective radiating area, and, where applicable, the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity, pulse duration, pulse repetition rate, focal area, and focal length. The errors in indications specified in paragraphs (c)(1) and (c)(2) of this section shall be stated in the instruction manual.

(iv) A listing of controls, adjustments, and procedures for operation and maintenance, including the warning "Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy."

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f))

[43 FR 7166, Feb. 17, 1978; 45 FR 16483, Mar. 14, 1980]

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